

(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bcfd32930-walkerp1]; Bethany Stokes [(b) (6)]

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200916.pdf

Location: <https://fnih.zoom.us/> (b) (6)

Start: 9/17/2020 5:00:00 PM

End: 9/17/2020 6:00:00 PM

Show Time As: Tentative

Recurrence: (none)
every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Garner, Carl; Mellors, John; Levy, Elliot; Menon, Sandeep; Sizemore, Christine (NIH/FIC) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butters, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6)

Optional Attendees: Anderson, Margaret; Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes

Stacey Adam is inviting you to a scheduled Zoom meeting.

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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] | (b) (6) Colvis, Christine (NIH/NCATS) [E] | (b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) : Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas | (b) (6) | Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar | (b) (6) |; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) | (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)

CC: (b) (6) (b) (6) (b) (6)

Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin | (b) (6) |; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria | (b) (6) Kim, Elizabeth | (b) (6) btolman | (b) (6) Wachtel, Jonathan | (b) (6) Prabhavathi Fernandes | (b) (6) Diamond, Michael | (b) (6) Rose Li | (b) (6) Dana Carluccio | (b) (6) |; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
 | (b) (6) Dave Frankowski | (b) (6) antoinette_baric
 | (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
 | (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Mason, Stephen
 | (b) (6) Connelly, Sarah | (b) (6) (b) (6) Lumsden, Joanne
 (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd
 | (b) (6) Hawk, Harrison | (b) (6) (b) (6)
 (b) (6) Gonzalez, Nina | (b) (6)

Start: 1/6/2021 3:00:00 PM
End: 1/6/2021 4:00:00 PM

Recurrence: (none)

Sent: 4/16/2020 12:38:01 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

Paul, Steve < (b) (6) >
Payne, David < (b) (6) >
Santos, Nancy < (b) (6) >

From: Myles, Renate (NIH/OD) [E] < (b) (6) >
Sent: Thursday, April 16, 2020 8:36 AM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Cc: Wolinetz, Carrie (NIH/OD) [E] < (b) (6) >
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

Unfortunately, I never received that list, but water under the bridge. It's been sent. Would you make sure to copy me on any updates to the list?

From: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Sent: Thursday, April 16, 2020 8:31 AM
To: Myles, Renate (NIH/OD) [E] < (b) (6) >
Cc: Wolinetz, Carrie (NIH/OD) [E] < (b) (6) >
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

The list was compiled yesterday morning by FNIH without any names, only emails. I wanted to double check the emails FNIH provided with names of the reps on the 4 ACTIV WGs along with the reps who participated in the April 3rd PPP meeting.

I found 8 emails that were missing and shared this with FC yesterday afternoon. Andy Plump was among the 8 which explains why his email was missing.

You now have the updated list – please let me know if you need anything else.

Ashley

From: Myles, Renate (NIH/OD) [E] < (b) (6) >
Sent: Thursday, April 16, 2020 8:15 AM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Cc: Wolinetz, Carrie (NIH/OD) [E] < (b) (6) >
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

I used the master list that you sent to him earlier in the week and Takeda wasn't in there. I never received an updated version of the master list.

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Thursday, April 16, 2020 8:14 AM
To: Myles, Renate (NIH/OD) [E] <(b) (6)>
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

Here is the updated list – seems FC used your emails and not the master list.

From: Myles, Renate (NIH/OD) [E] <(b) (6)>
Sent: Thursday, April 16, 2020 8:10 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

I pulled the names from the attached that you sent earlier in the week. There isn't a Takeda contact on this list. Would you send it to me?

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Thursday, April 16, 2020 8:03 AM
To: Myles, Renate (NIH/OD) [E] <(b) (6)>
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

Good morning Renate,

Our rep at Takeda, Andy Plump is included on the master list. I am confirming with Francis that he used our master list for his email that went out last night – **I should be able to confirm this for you this morning.**

I hope you are staying safe and healthy; maybe even getting some rest in between the constant COVID activities.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] <(b) (6)>
Sent: Thursday, April 16, 2020 7:14 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>
Subject: FW: PLEASE READ: Draft Email to Collect Communication Contact Information
Importance: High

Hi Ashley:

I'm not sure if Francis added a Takeda contact to his email. I could not find one on the master contact list. I have not heard from their organizations yet. Would you let me know if you provided that to him last night or if they are missing from this email? Need to send it to this group this morning.

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E]
Sent: Wednesday, April 15, 2020 9:11 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>

Cc: Wood, Gretchen (NIH/OD) [E] < (b) (6) > McManus, Ayanna (NIH/OD) [E]
(b) (6) Burklow, John (NIH/OD) [E] (b) (6) Parker,
Ashley (NIH/OD) [E] (b) (6)
Subject: PLEASE READ: Draft Email to Collect Communication Contact Information
Importance: High

Hi Francis:

We need to collect the communication contacts from the partner organizations so we can share the release with them for review. Below is 1) a draft email for you to send to the company participants, 2) the contacts for the companies we list in the release except for Takeda (I could not find a Takeda contact on the master list; hoping Ashley can provide); 3) those who should be copied (feel free to add others).

Dear ACTIV colleagues:

As I mentioned earlier today, we would like to announce the plans for a public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at (b) (6) and Abbey Meltzer (b) (6) this evening, if possible.

BCC:

(b) (6)

CC:

(b) (6)

Thanks,
Renate

To: Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)

(b) (6) ; (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];

(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] ; (b) (6) Colvis, Christine (NIH/NCATS) [E] ; (b) (6) Hewitt, Judith (NIH/NIAID) [E] ; (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];

(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];

(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) ; (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp];

(b) (6) Frank. (b) (6) Rao, Srinivas [(b) (6)

CC: Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Jonson, Samantha

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[(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6)]; Wachtel,
Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Rose Li
[(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
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[(b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

From: John Lepore (b) (6)
Sent: 4/9/2020 12:38:28 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: URGENT: Invitation to join the Vaccines Working Group of the COVID PPP

Dear Francis -

Thank you very much for sponsoring this critical initiative and for enabling GSK to contribute.

Please do reach out if you see any other way we could be of help.

With best wishes -

John

John Lepore
SVP, Head of Research

GSK
1250 S. Collegeville Road, Mail Code UP4-4400, Collegeville, PA 19426, US
Email (b) (6)
Tel (b) (6)
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From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, April 08, 2020 8:27 PM
To: Emmanuel Hanon <(b) (6)>
Cc: Melencio, Cheryl (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> John Lepore <(b) (6)>
Subject: URGENT: Invitation to join the Vaccines Working Group of the COVID PPP

EXTERNAL

Dear Dr. Hanon,

Addressing the COVID 19 pandemic is an urgent priority for the entire biomedical research community. Appropriately, the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond. But there is still no proven treatment, and safe and effective vaccines are many months away.

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and a vaccine candidate. But given the seriousness of this global public health crisis, it is time to broaden the response and create a focused public-private partnership with FDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics. This past Friday I led an initial discussion convened by the Foundation for the National Institutes of Health (FNIH) to decide on the initial research agenda for the partnership. There was broad support from all sectors for this model with some harkening back to a similar partnership that led to the development of antivirals for HIV/AIDS many years ago. Inspired by the shared embrace of a call to action, we are immediately launching efforts to collaborate in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development. Those four areas, and a summary of the meeting, are described in the attached document.

Each area will be powered by a nimble Working Group that includes appropriate domain expertise drawn from among our stakeholders. **You have been recommended to us by John Lepore as a member of the Vaccines Working Group.** The primary objective of this working group is to provide a collaborative framework for advancing vaccine development. I expect this will require a significant investment of your time when I know time is scarce. But these very serious circumstances call for full dedication to action from us all. I am personally committed to doing everything possible to support the execution of this partnership, and would be deeply appreciative if you will contribute your talents to this important effort.

Please direct your response to this invitation by Thursday April 9 (tomorrow! sorry this is such short notice) at 12pm EDT to Cheryl Melencio (b) (6). You may send any questions to Mike Santos (b) (6) at FNIH. A calendar invitation to the initial meeting of the Working Group will be sent out shortly after the response deadline.

I look forward to working with you on this critical effort.

Best,
Francis S. Collins, M.D., Ph.D.
Director, NIH

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/3/2020 6:30:35 PM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Na mish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Sarath n, Carla [(b) (6)]; (b) (6) [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Attachments: ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-Tally.xlsx

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Please find attached the final tally of scores for the agents that came through triage in Wave 1. We will use this document for our discussions today.

For those who sent me comments, I did not want to over whelm the score sheet will multiple rows of information. However, I have those and i will include them in the final record for posterity for this round. You can also feel free to bring them up during the discussion if helpful to the group.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[(b) (6)

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Attachments: PRECLINICAL_Working Group_Agenda_20200527_d3.pptx

Hi all,

Apologies – attached is the agenda along with a preliminary overview of our Preclinical Mid-term Plan as well as an updated timeline for our discussion today.

Look forward to our discussion today.

Regards,
Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: (b) (6)
www.deloitte.com

From: Alvarez, Rosa Maria

Sent: Wednesday, May 27, 2020 8:17 AM

To: Menetski, Joseph (FNIH) [T] <(b) (6) david.j (b) (6) (b) (6)>
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) Baric, Ralph <(b) (6) (b) (6) Ottinger,
Elizabeth (NIH/NCATS) [E] <(b) (6) Colvis, Christine (NIH/NCATS) [E] <(b) (6)
Hewitt, Judith (NIH/NIAID) [E] <(b) (6) Deming, Damon (FDA/CDER) <(b) (6)
(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]
<(b) (6) Collins, Francis (NIH/OD) [E] <(b) (6) (b) (6)
Adams, Peter (OS/ASPR/BARDA) <(b) (6) Rao, Srinivas <(b) (6) Qashu, Felicia
(NIH/OD) [E] <(b) (6) Tomas Cihlar <(b) (6) Pitt, Margaret L CIV USARMY
MEDCOM USAMRIID (USA) <(b) (6)
Cc: Wholley, David (FNIH) [T] <(b) (6) Austin, Christopher (NIH/NCATS) [E] <(b) (6)
Melencio, Cheryl (FNIH) [T] <(b) (6) Desrosiers, Betsy <(b) (6) Hughes, Eric
<(b) (6) Jansen, Kathrin <(b) (6) Kurilla, Michael (NIH/NCATS) [E]
<(b) (6) Lowy, Douglas (NCI) <(b) (6) Read, Sarah (NIH/NIAID) [E] <reads@niaid.nih.gov>;
Tountas, Karen (FNIH) [T] <(b) (6) Santos, Michael (FNIH) [T] <(b) (6) Adam, Stacey (FNIH) [T]
<(b) (6) James, Stephanie (FNIH) [T] <(b) (6) Kim, Elizabeth <(b) (6) Tolman,
Brett <(b) (6) Wachtel, Jonathan <(b) (6) Prabhavathi Fernandes
<(b) (6) Diamond, Michael <(b) (6) Rose Li
<(b) (6) Dana Carluccio <(b) (6) Lagos, Enrique (NIH/NCATS) [E]
<(b) (6) Jonson, Samantha (NIH/NCATS) [E] <(b) (6) Gonzalez, Nina
<(b) (6) Simon, Dina (NIH/OD) [C] <(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E]
<(b) (6) Rodriguez, Robin D <(b) (6) Dave Frankowski
<(b) (6) Baric, Toni C <(b) (6) Lowy, Douglas (NIH/NCI) [E]

< (b) (6) Florence, Clint (NIH/NIAID) [E] < (b) (6) Nancy Haigwood

< (b) (6) Stratton, Benjamin < (b) (6)

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Hi all,

Please find attached our agenda for today's meeting and the summary notes from our Friday meeting.

Look forward to our discussion today.

Regards,

Joe and Rosa

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] < (b) (6)

Sent: Tuesday, April 14, 2020 6:44 PM

To: Menetski, Joseph (FNIH) [T];

(b) (6) (b) (6) (b) (6) lay (b) (6)
(b) (6) ; Baric, Ralph; (b) (6) ; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine
(NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6)
(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
(b) (6) g; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas
Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy;
Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/N AID) [E].
Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa
Maria, Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes, Diamond, Michael; Rose Li, Dana
Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C];
Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski, Baric, Toni C; Lowy, Douglas (NIH/NCI) [E];
Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/j> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Sent: 7/22/2020 5:55:41 PM
Subject: FW: Summary of Communications Rollout plan for ACTIV clinical trials
Attachments: Summary_Rollout_ACTIV_Tx_Vaccines_7.22.2020.docx

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Wednesday, July 22, 2020 1:50 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane
<(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]
<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael <(b) (6)> Erbeling,
Emily (NIH/NIAID) [E] <(b) (6)> Erck, Stan <(b) (6)> Fauci, Anthony (NIH/NIAID) [E]
<(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gadbois, Ellen (NIH/OD) [E]
<(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Hudson, Thomas
<(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Johnson, Robert (OS/ASPR/BARDA)
<(b) (6)> Kramer, Lynn <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Lepore, John <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary
(NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David
<(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD)
<(b) (6)> Pandya, Hitesh <(b) (6)> Pangalos, Mene
<(b) (6)> Pao, William <(b) (6)> Parker, Ashley (NIH/OD) [E]
<(b) (6)> Paul, Steve <(b) (6)> Perlmutter, Roger <(b) (6)>
Plenge, Robert <(b) (6)> Plump, Andy <(b) (6)> Rachel Ramoni
<(b) (6)> Rasi, Guido <(b) (6)> Reed, John <(b) (6)> Reese, David
<(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Skovronsky,
Daniel <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul
<(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Talley, Michael
<(b) (6)> Tsai, John <(b) (6)> Vessey, Rupert <(b) (6)> Virgin, Skip
<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Woodcock, Janet (FDA/CDER)
<(b) (6)> Young, John <(b) (6)> Colvis, Christine (NIH/NCATS) [E]
<(b) (6)> Desrosiers, Betsy <(b) (6)> Eric Hughes
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>
Young, John <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)>
Castillejos, Carlos <(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Myles, Renate
(NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Adam, Stacey (FNIH) [T]
<(b) (6)> Alvarez, Rosa <(b) (6)> Anderson, Margaret <(b) (6)>
Chen, Helen <(b) (6)> Elsaid, Olivia <(b) (6)> Gonzalez, Nina
<(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T]
<(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Stratton, Ben <(b) (6)>
Tolman, Brett <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan
<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Meltzer, Abbey (FNIH) [T]
<(b) (6)> Gorman, Greta (FNIH) [T] <(b) (6)>
Subject: Summary of Communications Rollout plan for ACTIV clinical trials

Dear Leadership Team members and associated staff:

As noted on our last Leadership Team call we are planning to begin launching shortly a series of master protocols designed or otherwise supported through ACTIV to test therapeutics and vaccines for COVID-19. Attached is the current draft summary of the communications plan for all of these activities. As noted, it will consist initially of a "treatment page" on the NIH ACTIV website that will provide an updated on ACTIV's progress and a general preview of the protocols that are planned, which will then be followed by a rollout of individual specific press releases and other media on each master protocol as it actually launches.

Although the NIH Communications team is working with the individual companies whose drugs are being tested to review detailed materials as they are created, they will not have time or resources to seek detailed feedback on the wording of press materials from every partner involved in ACTIV. However, you may share this summary with your organization's communications staff and they may contact Renate Myles (b) (6) at NIH if they have any questions.

We look forward to what should be a very exciting month for ACTIV!

Regards,
David Wholley

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNHI earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/19/2020 6:55:16 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Sandeep Menon [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6) [(b) (6) [(b) (6) [(b) (6) [(b) (6) [(b) (6) wil [(b) (6) Eron, Joe [(b) (6) Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li [(b) (6) Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]
CC: Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [(b) (6) Eron, Joseph J Jr [(b) (6) Smith, David [(b) (6) Paul Klekotka [(b) (6) Ajay Nirula [(b) (6) Elsaid, Olivia [(b) (6)
Subject: RE: Confirmed: ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting
Attachments: ACTIV Therapeutics-Clinical mAb outpatient MP 19May2020 Agenda pdf; a5401-d03-activ-051620_Lilly_Paul_Klekotka.docx

Dear ACTIV-2 Writing Team,

Please see the suggested attached agenda.

In addition, I am circulating a draft of the protocol with some comments from our Lilly colleagues. Looking forward to seeing you all in about an hour.

Thanks,

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

APAR0000005369-2517592

Direct: (b) (6) Mobile: (b) (6)

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/29/2020 11:50:25 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: Key messages re. immunomodulators for slides for Moncef meeting tomorrow 5/30

Many thanks. I await the masterpiece.

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Friday, May 29, 2020 7:41 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)>; Freire, Maria (FNIH) [T] <(b) (6)>; Gonzalez, Nina [T] <(b) (6)>; Parker, Ashley (NIH/OD) [E] <(b) (6)>; Freire, Maria (FNIH) [T] <(b) (6)>
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Have seen and offered a few changes to the complete slide deck. They should be coming back to you as soon as Deloitte makes the changes.

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Friday, May 29, 2020 5:59 PM
To: Wholley, David (FNIH) [T] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)>; Freire, Maria (FNIH) [T] <(b) (6)>; Gonzalez, Nina [T] <(b) (6)>; Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note – has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

From: Wholley, David (FNIH) [T] (b) (6)
Sent: Friday, May 29, 2020 1:59 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Adam, Stacey (FNIH) [T] (b) (6) ; Freire, Maria (FNIH) [T] (b) (6) >; Gonzalez, Nina (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6)
Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1, it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
 - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
 - ACTIV hiVIG (sponsored by NIAID) – in progress
 - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
 - ACTIV-2* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
 - ACTIV-3* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
 - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) – (Phase II/III) – projected launch late June
 - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (*if needed, i.e. if agents are not incorporated into mAb protocols*)
 - * current priority

[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
 - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
 - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
 - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
 - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)

- Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
- Protocol is 80% complete
 - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
 - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
 - All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- “ACTIV-4” Protocol for anticoagulants
 - Need bullets from NHLBI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
 Senior Vice-President, Research Partnerships
 Foundation for the National Institutes of Health

(b) (6)

fnh.org
 11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNHI earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 4/27/2020 9:49:48 PM
To: (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas
| (b) (6) |
CC: Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Diamond, Michael
| (b) (6) Rodriguez, Robin D | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
| (b) (6) Hughes, Eric | (b) (6) Jansen, Kathryn
| (b) (6) |; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4b79577e2aa8d1-jamesst]; Alvarez, Rosa Maria
| (b) (6) |; Kim, Elizabeth | (b) (6) Tolman, Brett | (b) (6) Wachtel,
Jonathan (b) (6) Prabhavathi Fernandes | (b) (6) Rose Li
| (b) (6) Dana Carluccio | (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];

Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Dave Frankowski | (b) (6) Baric, Toni C | (b) (6)

Subject: Canceled: ACTIV Preclinical working group (Tuesday meeting)

Location: <https://fnih.zoom.us/> (b) (6)

Start: 4/28/2020 6:00:00 PM

End: 4/28/2020 7:00:00 PM

Show Time As: Free

Recurrence: Weekly
every Tuesday from 2:00 PM to 3:00 PM

Required Attendees: (b) (6)

(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas Lowy, Douglas (NIH/NCI) [E]; Diamond, Michael; Rodriguez, Robin D; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Dave Frankowski; Baric, Toni C

We are planning several smaller individual workstream meetings instead of the full working group. We will provide updates from the individual workstreams the next full Working group meeting (Thursday, 11-12 Eastern time).

Joe

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Find your local number: <https://fnih.zoom.us> (b) (6)

From: Tountas Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40c04fef6f1e46f5b750753cd5a14f93-TOUNTASKH]
Sent: 5/22/2020 5:59:49 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel
 | (b) (6) Cohen, Myron | (b) (6) Corey, Larry | (b) (6)
 Victoria Davey | (b) (6)]; Desrosiers, Betsy | (b) (6) Dickens, Jim
 (NIH/NCATS) [C] (b) (6) Doroshov, James (NIH/NCI) [E] | (b) (6) Garner, Carlos
 | (b) (6) Goff, David (NIH/NHLBI) [E] | (b) (6) Kurilla, Michael (NIH/NCATS) [E]
 | (b) (6) Mensah, George (NIH/NHLBI) [E] | (b) (6) Nayak, Seema (NIH/NIAID) [E]
 | (b) (6) Payton, Manizhe (NIH/NIAID) [E] | (b) (6) Resnansky, Laura
 [resnansky (b) (6) Sizemore, Christine (NIH/FIC) [E] | (b) (6) Srinivasan, Badhri
 | (b) (6) Stein, Peter (FDA/CDER) | (b) (6) Vincent, Mike
 | (b) (6) Weinmann, Gail (NIH/NHLBI) [E] | (b) (6) Kublin MD, MPH, James
 (b) (6) Ferguson, Sue | (b) (6)
CC: Wachtel, Jonathan | (b) (6)], Colvis, Christine (NIH/NCATS) [E] [christi (b) (6)]. Hughes,
 Eric | (b) (6) Jansen, Kathrin | (b) (6)]; Lowy, Douglas (NCI) | (b) (6)];
 Read, Sarah (NIH/NIAID) [E] | (b) (6) Young, John | (b) (6) Adam, Stacey (FNIH)
 [T] | (b) (6) Anderson, Margaret | (b) (6) Parker, Ashley (NIH/OD) [E]
 | (b) (6) Carluccio, Dana | (b) (6) Melencio, Cheryl (FNIH) [T]
 | (b) (6) Gonzalez, Nina | (b) (6) Heaton, Penny | (b) (6)
 James, Stephanie (FNIH) [T] | (b) (6) Li, Rose | (b) (6) Menetski, Joseph (FNIH) [T]
 (b) (6) Qashu, Felicia (NIH/OD) [E] | (b) (6) Santos, Michael (FNIH) [T]
 | (b) (6) Tuvevsson, Nancy | (b) (6) Wholley, David (FNIH) [T]
 | (b) (6) Criffield, Robin | (b) (6) Hamilton, Nancy
 | (b) (6) Hill, Zoe (NIH/NHLBI) [C] | (b) (6) Minnich, Beth
 | (b) (6) Mueller-Reichenstein, Petra | (b) (6) Pico, Dianna
 (NIH/NHLBI) [C] | (b) (6) Quadros, Nora | (b) (6) Katz, Rebecca (NIH/NCATS) [E]
 | (b) (6) Culp, Michelle (NIH/OD) [E] | (b) (6) Gadbois, Ellen (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Kenny, Dermot
 | (b) (6) (b) (6)

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment
Location: <https://fnih.zoom.us/> (b) (6)
Start: 6/2/2020 1:00:00 PM
End: 6/2/2020 2:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
 every Tuesday from 9:00 AM to 10:00 AM
Required Attendees: Tountas Karen (FNIH) [T]; Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manizhe; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Vincent, Mike; Weinmann, Gail; Kublin MD, MPH, James; Ferguson, Sue
Optional Attendees: Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E]
 | (b) (6) Carluccio, Dana; Cheryl (FNIH) Melencio [T] | (b) (6) Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuvevsson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI) [C]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] | (b) (6)
 Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Kenny, Dermot; (b) (6)

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate - looking forward to operationalizing the outcomes of your efforts. Let's continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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US (Tacoma)

US (Houston)

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Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 4/22/2020 1:00:37 AM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner | (b) (6) Keith Gottesdiener | (b) (6) Eric Hughes | (b) (6) LaVange, Lisa M | (b) (6) Elliott Levy | (b) (6) Sandeep Menon | (b) (6) Amanda Peppercorn | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn | (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael | (b) (6)

CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan | (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US (b) (6)

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #5

Location: <https://fnih.zoom.us/> (b) (6)

Start: 4/22/2020 6:00:00 PM

End: 4/22/2020 7:00:00 PM

Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylvia (FDA/CDER); Judy Carrier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael

Optional Attendees: Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

Stacey Adam is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/24/2020 11:23:21 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner | (b) (6) Keith Gottesdiener | (b) (6) Eric Hughes | (b) (6) LaVange, Lisa M | (b) (6) Elliott Levy | (b) (6) Sandeep Menon | (b) (6) Amanda Peppercorn | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn | (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael | (b) (6) Wung, Peter /US | (b) (6)
CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskn]; Wachtel, Jonathan | (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #11

Location: <https://fnih.zoom.us/j> (b) (6)

Start: 4/29/2020 7:00:00 PM

End: 4/29/2020 8:00:00 PM

Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylvia (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US

Optional Attendees: Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Stacey Adam is inviting you to a scheduled Zoom meeting.

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Password: (b) (6)

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Jim Neaton [(b) (6) Jens Lundgren (b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Srinivasan, Badhri [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Victoria Davey [(b) (6) Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Tierney, John (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [(b) (6) Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla], wesley.self@yumc.org; Gelijns, Annetine [(b) (6) Mark Polizzotto [(b) (6) Ginny Kan [(b) (6)]; Baker, Jason [(b) (6) Roger Paredes [(b) (6) Thompson, Taylor, M.D. [(b) (6) Babiker, Ab [(b) (6) Ginde, Adit [(b) (6) Aileen Ilaria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=860a21fece5d4ff2b206b3d1856c06cf-AileenIlari]; Ringwood, Nancy J [(b) (6) Oldmixon, Cathryn F. [(b) (6) Moskowitz, Alan [(b) (6) Cahill, Kelly (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6de9c32a53a54a9eae9d9e5138a0ecc7-cahillke]; Vogel, Susan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a18354e56c6c45d5b4a9701770890c81-svogel]; Simpson, Shelly (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=371206262b394fecaab6f43a3a6f9de6-shsimpson]

CC: Grace, Beth (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Chen, Helen Q. [(b) (6) Wachtel, Jonathan [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A. [(b) (6) Kunlia, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkunlia]; Parker, Ashely (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Pett, Sarah [(b) (6) Barrett, Kevin (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrett2]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.cabr]; Eileen Denning
 | (b) (6) Baseler, Beth (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=2363525c118a468b9e8f5f61707c63f5-bbaseler]; Engel, Theresa (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e86305ea82754e65b67a63591ed867ba-engelt]; Lisbeth Jørgensen
 | (b) (6) RH-FP-INSIGHT014-ACTIV3 | (b) (6)
 Erhardt, William (HHS/IOS) | (b) (6) Judith Anne Gallagher
 | (b) (6) Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Kenny, Dermot
 | (b) (6) Grace, Beth (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]

Start: 7/7/2020 3:00:00 PM

End: 7/7/2020 4:00:00 PM

Recurrence: (none)

Required Attendees: Cahill, Kelly (NIH/NIAID) [E]; Vogel, Susan (NIH/NIAID) [E]; Jim Neaton; Jens Lundgren; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Higgs, Elizabeth (NIH/NIAID) [E]; Srinivasan, Badhri; Goff, David (NIH/NHLBI) [E]; Nayak, Seema (NIH/NIAID) [E]; Victoria Davey; Kozak, Marina (OS/ASPR/BARDA); McNay, Laura (NIH/NIAID) [E]; Tierney, John (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; Erhardt, William (HHS/IOS); Reineck, Lora (NIH/NHLBI) [E]; (b) (6) Gelijns, Annetine; Mark Polizzotto; Ginny Kan; Baker, Jason; Roger Paredes, Thompson, Taylor, M.D.; Babiker, Ab; Ginde, Adit; Aileen M Ilana; Ringwood, Nancy J; Oldmixon, Cathryn F.; Moskowitz, Alan; Simpson, Shelly (NIH) [C]

Optional Attendees: Kenny, Dermot; Chen, Helen Q.; Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Pett, Sarah; Grace, Beth (NIH/NIAID) [C]; Barrett, Kevin (NIH/NIAID) [E]; Denning, Eileen; Eileen Denning; Baseler, Beth (NIH) [C]; Engel, Theresa (NIH) [C]; Lisbeth Jørgensen; RH-FP-INSIGHT014-ACTIV3; Erhardt, William (HHS/IOS); Judith Anne Gallagher; Harrigan, Rachel (HHS/IOS)

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-ME.LENCIOC]
Sent: 1/12/2021 9:59:03 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] | (b) (6) Bancel, Stephane | (b) (6) Carter, Kara | (b) (6) Cavaleri, Marco | (b) (6) Cihlar, Tomas | (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry | (b) (6) Culp, Michelle (NIH/OD) [E] | (b) (6) Victoria Davey | (b) (6) Disbrow, Gary (OS/ASPR/BARDA) | (b) (6) Dolsten, Mikael | (b) (6) Erbeling, Emily (NIH/NIAID) [E] | (b) (6) Erck, Stan | (b) (6)]; Fauci, Anthony (NIH/NIAID) [E] | (b) (6) Gadbois, El en (NIH/OD) [E] | (b) (6) Gibbons, Gary (NIH/NHLBI) [E] | (b) (6) Hudson, Thomas | (b) (6)]; James, Stephanie (FNIH) [T] | (b) (6) Johnson, Robert (OS/ASPR/BARDA) | (b) (6)]; Kramer, Lynn | (b) (6) Lane, Cliff (NIH/NIAID) [E] | (b) (6) Lepore, John | (b) (6)]; Marks, Peter (FDA/CBER) | (b) (6)]; Marston, Hilary (NIH/NIAID) [E] | (b) (6)]; Mascola, John (NIH/VRC) [E] | (b) (6) Meeker, David | (b) (6) Menetski, Joseph (FNIH) [T] | (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) | (b) (6) Pandya, Hitesh | (b) (6) Pangalos, Mene | (b) (6) Pao, William | (b) (6) Parker, Ashley (NIH/OD) [E] | (b) (6) Paul, Steve | (b) (6) Perlmutter, Roger | (b) (6) Plenge, Robert | (b) (6)]; Plump, Andy | (b) (6) Rachel Ramoni | (b) (6) Reed, John | (b) (6) Reese, David | (b) (6)]; Rouse, Doris | (b) (6) Santos, Michael (FNIH) [T] | (b) (6) Skovronsky, Daniel | (b) (6) Stein, Peter (FDA/CDER) | (b) (6) Stoffels, Paul | (b) (6) Tabak, Lawrence (NIH/OD) [E] | (b) (6) Talley, Michael [michael.j.] | (b) (6) Tsai, John | (b) (6) Vessey, Rupert | (b) (6) Virgin, Skip | (b) (6) Wholley, David (FNIH) [T] | (b) (6) Woodcock, Janet (FDA/CDER) | (b) (6)]; Young, John | (b) (6) Colvis, Christine (NIH/NCATS) [E] | (b) (6) Desrosiers, Betsy | (b) (6) Eric Hughes | (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E] | (b) (6) Lowy, Douglas (NCI) | (b) (6)]; Read, Sarah (NIH/NIAID) [E] | (b) (6) Adam, Stacey (FNIH) [T] | (b) (6) Margaret Anderson | (b) (6) Appell, Evan | (b) (6) Chen, Helen | (b) (6) Connelly, Sarah | (b) (6)]; Gonzalez, Nina | (b) (6) Hawk, Harrison | (b) (6)]; Mendelson, Jesse | (b) (6)]; Nasr, Hana | (b) (6) Sorosa, Alex | (b) (6) Stratton, Benjamin | (b) (6)]; btolman | (b) (6) Wachtel, Jonathan | (b) (6)]; Anderson, James (NIH/OD) [E] | (b) (6) Burklow, John (NIH/OD) [E] | (b) (6)]; Carluccio, Dana | (b) (6) Castilejos, Carlos | (b) (6)]; FNIH Central Account | (b) (6) Hallett, Adrienne (NIH/OD) [E] | (b) (6) Lumsden, Joanne | (b) (6) Myles, Renate (NIH/OD) [E] | (b) (6) Wolinetz, Carrie | (b) (6) Meltzer, Abbey (FNIH) [T] | (b) (6) Austin, Sarah (NIH/NIAID) [E] | (b) (6)]; Barasch, Kimberly (NIH/NIAID) [C] | (b) (6) Bell, Julie | (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [cyndi.burrus-shaw@nih.gov]; Carver, Trea (NIH) [C] | (b) (6) Caulfield, Anita | (b) (6)]; Coan, Amanda | (b) (6) Conrad, Patricia (NIH/NIAID) [E] | (b) (6) Dimishkov, Roxanne | (b) (6) Edl, Susan | (b) (6) Fuhrer, Nicole | (b) (6) Giorgi, Sara | (b) (6) Hoban, Michelle | (b) (6)]; Hoffstetter, Renata (FNIH) [T] | (b) (6) Iderdema, Vaide | (b) (6) Jenkins, Christine S. | (b) (6) Lagos, Enrique (NIH/NCATS) [E] | (b) (6) Lever, Susan | (b) (6) Magbie-Robinson, Kim (NIH/OD) [C] | (b) (6) Martin, Melisa | (b) (6) McManus, Ayanna (NIH/OD) [E] | (b) (6) Minnich, Beth | (b) (6) Perala, Mie | (b) (6) Protasiewicz, Ann | (b) (6)]; Riccobene, Kim | (b) (6) Riffin, Mary | (b) (6)]; Ripley, Nadege | (b) (6) Schuster, Donna | (b) (6) Sepulveda, Dorina (FNIH) [T] | (b) (6) Simon, Dina (NIH/OD) [C] | (b) (6) Suhana, Tina (NIH/VRC)

[E] [(b) (6)	Thomas, Ashley (FDA/CDER)	(b) (6)	Wood, Gretchen (NIH/OD)
[E] [(b) (6)	Togashi, Mieko (NIH/NCI) [E]	(b) (6)	Underwood, Nancy
[(b) (6)	Zottoli, Jessica	(b) (6)	Hughes, Karen (NIH/OD) [E]
[(b) (6)	Regan, Donna M	(b) (6)	Plenge, Robert (b) (6)

Subject: ACTIV Leadership Team Call #16

Location: <https://fnih.zoom.us/j> (b) (6)

Start: 5/28/2021 1:00:00 PM

End: 5/28/2021 2:30:00 PM

Show Time As: Tentative

Required Attendees: Melencio, Cheryl (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaler, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, El en (N H/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER), Marston, H lary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, Wi liam; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris, Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael, Tsai, John; Vessey, Rupert, Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kuril a, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse, Nasr, Hana, Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan, Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Meltzer, Abbey (FNIH) [T]

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea, NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorg., Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T] Iberdemaj, Vaide; Jenk ns, Christine S.; Krack, Kimberly, Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan, Magbie-Robinson, K m (NIH/OD) [C]; Martin, Melisa, McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggins, Mary, Ripley, Nadege, Schuster, Donna, Sepulveda, Dorina (FNIH) [T], Simon, Dina (NIH/OD) [C], Suhana, T na (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Hughes, Karen (NIH/OD) [E]; Magbie-Robinson, Kim; Regan, Donna M; Plenge Robert

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/20/2020 6:42:35 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: did you get an invite for the July 15 Exec Comm meeting?

Hi Michelle,

It dawned on me too late that I didn't have the July 15 ACTIV Executive Committee Teleconference on my calendar. I got the slides from David in the email below, but I don't think I ever got the invitation. Did you get the invitation? I shouldn't miss the next one.

Thanks,
Ellen

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, July 14, 2020 8:44 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>
Dolsten, Mikael <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Pao, William <(b) (6)>
Plump, Andrew <(b) (6)> Stoffels, Paul <(b) (6)>
Woodcock, Janet (FDA/CDER) <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)>
Desrosiers, Betsy <(b) (6)> Eric Hughes <(b) (6)>
Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)>
Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>
Young, John <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)>
Burklow, John (NIH/OD) [E] <(b) (6)> Castillejos, Carlos <(b) (6)>
Culp, Michelle (NIH/OD) [E] <(b) (6)> FNIH Central Account <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>
Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)>
Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)>
Parker, Ashley (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)>
Alvarez, Rosa <(b) (6)> Anderson, Margaret <(b) (6)>
Chen, Helen <(b) (6)> Elsaid, Olivia <(b) (6)> Gonzalez, Nina <(b) (6)>
James, Stephanie (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)>
Santos, Michael (FNIH) [T] <(b) (6)> Stratton, Ben <(b) (6)>
Tolman, Brett <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)>
Wholley, David (FNIH) [T] <(b) (6)> Gorman, Greta (FNIH) [T] <(b) (6)>
Meltzer, Abbey (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)>

Subject: Materials for July 15 ACTIV Executive Committee Teleconference

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 PM to 4:30 PM Eastern U.S. time tomorrow, Wednesday July 15. I have also attached notes from our July 1 Leadership Team meeting as well as our last EC meeting on June 17.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

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From: Connelly, Sarah | (b) (6)
Sent: 3/2/2021 10:24:20 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
(b) (6) | (b) (6) | (b) (6) | (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) | (b) (6) | (b) (6) | Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
(b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n], Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Prabhavathi Fernandes [(b) (6) Diamond, Michael | (b) (6) Rose Li [(b) (6) Dana Carluccio | (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D | (b) (6) Dave Frankowski | (b) (6) antoinette baric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoonoh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen | (b) (6) (b) (6) (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd | (b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

Dear Preclinical Working Group Members,

Please see below for the agenda for tomorrow's meeting at 10:00 AM ET. If you have any questions or items to add, please let us know.

Agenda Topic	Duration	Facilitator
Tulane NHP Studies CoV Coordinating Center – update	15 mins	Jay Rappaport
Post-Acute Sequelae of SARS-CoV-2 infection (PASC), i.e., long haulers, strategy subgroup Kick-off	15 mins	Jay Rappaport
Subgroup Updates		
o Data portal implementation		Sam Jonson
o NHP Field Guide	15 mins	John Young
o Preclinical prioritization		Joe Menetski
o Emerging Viral Variants		
Align on action items and next steps	10 mins	Joe Menetski Sarah Connelly

Warm Regards,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: (617) 345-1234
www.deloitte.com

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] <(b) (6)>

Sent: Friday, October 2, 2020 2:19 PM

To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E];

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Baric, Ralph;

(b) (6)

Ottinger, Elizabeth (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith

(NIH/NIAID) [E]; Deming, Damon (FDA/CDER);

(b) (6)

(b) (6)

(b) (6)

Parker, Ashley (NIH/OD) [E];

(b) (6)

Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu,

Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA), Punturieri, Antonello

(NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E];

(b) (6)

(b) (6)

Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Eric

Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas,

Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria;

Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio;

Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-

Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D, Dave Frankowski, antoinette_baric, Lowy, Douglas (NIH/NCI) [E];

Florence, Clint (NIH/NIAID) [E]; Nancy Halgwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James

(NIH/OD) [E]; Hawk, Harrison; Mason, Stephen;

(b) (6)

Connelly, Sarah;

(b) (6)

Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd;

(b) (6)

Subject: ACTIV Preclinical full working group

When: Wednesday, March 3, 2021 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/j/>

(b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://fnih.zoom.us/j/>

(b) (6)

Meeting ID: (b) (6)

Passcode: (b) (6)

One tap mobile

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US (Washington D.C.)

US (Chicago)

Dial by your location

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US (Washington D.C.)

US (Chicago)

US (New York)

US (San Jose)

US (San Jose)

US (Tacoma)

US (Houston)

Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us>, (b) (6)

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/17/2020 6:10:12 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: ChAdOx1
Flag: Follow up

How should we handle this? I think we agreed that calling out Kathrin at this point would likely not be productive. If this is a call to discuss getting Pfizer's vaccine on board, that is another matter. Thoughts?

From: Marks, Peter <(b) (6)>
Sent: Saturday, May 16, 2020 3:13 PM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)>
Collins, Francis (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: ChAdOx1

Dear Tony,

Will certainly include you next week on this call.

Best Regards,
Peter

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 9:12 AM
To: Marks, Peter <(b) (6)> Mascola, John R (NIH) <(b) (6)> >; Collins, Francis S (NIH) <(b) (6)> >; Lane, Henry C (NIH) <(b) (6)> >
Cc: Wholley, David N (NIH) <(b) (6)> ; Tabak, Lawrence A (NIH) <(b) (6)> Parker, Ashley S (NIH) <(b) (6)>
Subject: RE: ChAdOx1

I would also like to be on that call with the Pfizer CEO if we could possible arrange it.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b) (6)

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COLL0000016959- (b) (6)

From: Marks, Peter <(b) (6)>
Sent: Thursday, May 14, 2020 9:05 AM
To: Mascola, John (NIH/VRC) [E] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Cc: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> ; Wholley, David (FNIH) [T] <(b) (6)> ; Tabak, Lawrence (NIH/OD) [E] <(b) (6)> ; Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: ChAdOx1

Dear John,

Thanks for bringing the Pfizer issue up. I think that a call with their head of development and possibly also their CEO may be needed, and I wonder if Francis would like to join?

Best Regards,
Peter

From: Mascola, John (NIH/VRC) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 9:03 AM
To: Marks, Peter <(b) (6)> Collins, Francis S (NIH) <(b) (6)> Lane, Henry C (NIH) <(b) (6)>
Cc: Fauci, Anthony S (NIH) <(b) (6)> ; Wholley, David N (NIH) <(b) (6)> Tabak, Lawrence A (NIH) <(b) (6)> ; Parker, Ashley S (NIH) <(b) (6)>
Subject: RE: ChAdOx1

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issues is that the Pfizer representative on the subgroup, both Kathrin Jansen (who is co-chair of Vaccines WG), and Bill Gruber (Pfizer Senior VP for R&D) – took turns articulating their view that large Pharma companies like theirs prefer not to work with USG and it would just slow them down. When we asked for suggestions for DSMB, Kathrin said she did not agree that we should ask for nominations – because this issue required more discussion – mainly because Pfizer has no interest in this. Doug Lowy was on the call, so may be useful to get his perspective.

John

From: Marks, Peter <(b) (6)>
Sent: Thursday, May 14, 2020 6:23 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Cc: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> ; Wholley, David (FNIH) [T] <(b) (6)> ; Tabak, Lawrence (NIH/OD) [E] <(b) (6)> ; Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: ChAdOx1

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that (b) (5)
(b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5) Happy to discuss further.

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E] (b) (6) >
Sent: Thursday, May 14, 2020 5:38 AM
To: Mascola, John R (NIH) (b) (6) ; Lane, Henry C (NIH) (b) (6) ; Marks, Peter <(b) (6)>
Cc: Fauci, Anthony S (NIH) <(b) (6)> Wholley, David N (NIH) <(b) (6)> Tabak, Lawrence A (NIH) (b) (6) ; Parker, Ashley S (NIH) (b) (6)
Subject: ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 6/6/2020 4:52:42 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures
Flag: Follow up

Dear Francis,

The meeting has these invites.

Wholley, David (FNIH) [T]
Adam, Stacey (FNIH) [T]
Menetski, Joseph (FNIH) [T]
Jacqueline Kirchner
Woodcock, Janet (FDA/CDER)
Collins, Francis (NIH/OD) [E]

joe

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Saturday, June 6, 2020 12:50 PM
To: Wholley, David (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Cc: Menetski, Joseph (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Sincere apologies, I just saw this message. I don't know who has been invited to join this call, can someone fill me in?

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Saturday, June 6, 2020 7:21 AM
To: Menetski, Joseph (FNIH) [T] <(b) (6)> ; Collins, Francis (NIH/OD) [E] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> ; Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Cc: Menetski, Joseph (FNIH) [T] <(b) (6)> ; Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: Re: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

I noticed a label on today's call "data shared in confidence". Does this give us pause in terms of inviting additional experts?

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From: Menetski, Joseph (FNIH) [T] <(b) (6)>
Sent: Friday, June 5, 2020 6:43:53 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T] (b) (6) >; Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear Francis,

Stacey and I have polled our working groups, asking for suggestions and volunteers that could provide expert opinion on monoclonal antibody testing during conversations with Skip Virgin and Jacqueline Kirchner. The groups are very enthusiastic about this topic and we received almost 30 names of experts in the field. Given the time frame that we are asking for people to join these calls, I have picked 4 people that are already involved in ACTIV to invite to the Jacqueline Kirchner call tomorrow and 6 to invite to the call with Skip on Monday.

As I said, there were many more, but I think we would want to talk to them first, before bringing them into a discussion like this.

I am happy to invite these folks tonight, if it would be easier and agreeable to you (I would cc you). Or I have drafted a short email for you to send them below (as always, feel free to modify).

Best regards,
Joe

Memo: ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear xx,

The NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership is setting up protocols to assess monoclonal neutralizing antibodies as therapies against COVID-19. During discussions with the ACTIV Leadership Team and in collaboration with the upcoming Monoclonal Antibody Round Table, we have a meeting to gather additional expert opinion on the appropriate preclinical testing approaches, particularly for choosing mixtures or cocktails of neutralizing Abs. I would like to have your input in the important topic during a meeting [tomorrow at 1pm ET; or Monday at 2 45pm ET]. I realize this is short notice, but the ACTIV program is moving very fast and our rapid response is essential. I hope you can join me in this important discussion.

Sincerely,
Francis Collins

Names and emails below.

Saturday call with J Kirchner:

Peter Adams, (OS/ASPR/BARDA); (b) (6)
Michael Diamond at Washington University at St Louis; (b) (6)
Kara Carter at EvoTec; (b) (6)
John W Mellors at University of Pittsburgh; (b) (6)

Monday call with Skip Virgin:

Peter Adams, (OS/ASPR/BARDA); (b) (6)
Michael Diamond at Washington University at St Louis; (b) (6)
Kara Carter at EvoTec; (b) (6)
John W Mellors at University of Pittsburgh; (b) (6)

Randall Tressler, (NIH/NIAID); (b) (6)
Sebastian Breuer, Roche, (b) (6)

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6) fnih.org

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From: Tucker, Jessica (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2BAF4AE78D90412DBEFBFFB5E52C31A4-TUCKERJM]
Sent: 12/18/2020 8:35:17 PM
To: Harris, Kathryn (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79d72a4a3dcb43e785c83411756cd9e7-HarrisKath]; O'Reilly, Marina (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54d6c68e99e94ea6bc7872cfbf0d0176-oreillym]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: ACTIV slides from today on escape mutations

Right, but it matters whether they realize what is or is not an MA .

From: Harris, Kathryn (NIH/OD) [C] < > (b) (6)
Sent: Friday, December 18, 2020 3:35 PM
To: Tucker, Jessica (NIH/OD) [E] < > (b) (6) O'Reilly, Marina (NIH/OD) [E] < > (b) (6)
Cc: Gadbois, Ellen (NIH/OD) [E] < > (b) (6)
Subject: RE: ACTIV slides from today on escape mutations

Well BARDA making grantees follow GLs (based on the vaccine stuff they had come to us)

From: Tucker, Jessica (NIH/OD) [E] < > (b) (6)
Sent: Friday, December 18, 2020 3:32 PM
To: O'Reilly, Marina (NIH/OD) [E] < > (b) (6) >; Harris, Kathryn (NIH/OD) [C] < > (b) (6)
Cc: Gadbois, Ellen (NIH/OD) [E] < > (b) (6)
Subject: FW: ACTIV slides from today on escape mutations

More from Ellen on this.

From: Gadbois, Ellen (NIH/OD) [E] < > (b) (6)
Sent: Friday, December 18, 2020 12:11 PM
To: Tucker, Jessica (NIH/OD) [E] < > (b) (6)
Subject: RE: ACTIV slides from today on escape mutations

And more from the FNIH/Deloitte call—Moncef Slaoui is going to ask BARDA for the funds for this project. FNIH is prepping a budget.

From: Gadbois, Ellen (NIH/OD) [E] < > (b) (6)
Sent: Friday, December 18, 2020 10:41 AM
To: Tucker, Jessica (NIH/OD) [E] < > (b) (6)
Subject: RE: ACTIV slides from today on escape mutations

More today on the ACTIV preclinical WG call: FYI this whole effort also includes escape mutants from the vaccines, not just the therapeutics. And I think the member from Roche said something like there are already mutations known to affect efficacy of cocktails (presumably of antibodies), but I am not sure I heard that right. At any rate, I keep hearing the FDA is requiring companies to generate this information.

From: Tucker, Jessica (NIH/OD) [E] < > (b) (6)
Sent: Wednesday, December 16, 2020 4:17 PM
To: Gadbois, Ellen (NIH/OD) [E] < > (b) (6)
Subject: RE: ACTIV slides from today on escape mutations

Thank you!

From: Gadbois, Ellen (NIH/OD) [E] (b) (6)
Sent: Wednesday, December 16, 2020 1:16 PM
To: Tucker, Jessica (NIH/OD) [E] (b) (6)
Subject: FYI: ACTIV slides from today on escape mutations

See slides 6-10. Note that slide 8 includes "selection screens." There was general enthusiasm on the call today for the general effort and FC asked industry members what they could do to help. Skip Virgin from VIR said that there are certain experiments that FDA is also asking sponsors to conduct and so centralizing assays and information was important. There was then discussion of a platform that FDA/BARDA/OWS has apparently already built that takes sequence data, makes pseudotype viruses, and run them against a panel of antibodies. (I had to look up pseudotyping—it sounds like it is making a replication incompetent virus.) Not much more detail.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 6:29 PM
To: Wholley, David (FNIH) [T] (b) (6); Austin, Christopher (NIH/NCATS) [E] (b) (6);
Bancel, Stephane (b) (6); Carter, Kara <(b) (6)>; Cavaleri, Marco
<(b) (6)>; Cihlar, Tomas (b) (6); Collins, Francis (NIH/OD) [E]
<(b) (6)>; Corey, Larry <(b) (6)>; Culp, Michelle (NIH/OD) [E] (b) (6)
Victoria Davey (b) (6); Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>; Dolsten, Mikael
(b) (6); Erbelding, Emily (NIH/NIAID) [E] <(b) (6)>; Erck, Stan
<(b) (6)>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>; Freire, Maria (FNIH) [T]
(b) (6); Gadbois, Ellen (NIH/OD) [E] <gagadboisel@od.nih.gov>; Gibbons, Gary (NIH/NHLBI) [E]
<(b) (6)>; Hudson, Thomas <(b) (6)>; James, Stephanie (FNIH) [T]
<(b) (6)>; Johnson, Robert (OS/ASPR/BARDA) <(b) (6)>; Kramer, Lynn
(b) (6); Lane, Cliff (NIH/NIAID) [E] (b) (6); Lepore, John (b) (6)
Marks, Peter (FDA/CBER) <(b) (6)>; Marston, Hilary (NIH/NIAID) [E] (b) (6);
Mascola, John (NIH/VRC) [E] <(b) (6)>; Meeker, David <(b) (6)>; Menetski, Joseph
(FNIH) [T] <jmenetski@fnih.org>; Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6); Pandya, Hitesh
<(b) (6)>; Pangalos, Mene <(b) (6)>; Pao, William
<william.pao@roche.com>; Parker, Ashley (NIH/OD) [E] (b) (6); Paul, Steve (b) (6)
Perlmutter, Roger <(b) (6)>; Plenge, Robert <(b) (6)>; Plump, Andy
<(b) (6)>; Rachel Ramoni <(b) (6)>; Reed, John (b) (6); Reese,
David <(b) (6)>; Rouse, Doris (b) (6); Santos, Michael (FNIH) [T] (b) (6)
Skovronsky, Daniel (b) (6); Stein, Peter (FDA/CDER) (b) (6); Stoffels, Paul
(b) (6); Tabak, Lawrence (NIH/OD) [E] <(b) (6)>; Talley, Michael
<(b) (6)>; Tsai, John (b) (6); Vessey, Rupert (b) (6); Virgin, Skip
(b) (6); Woodcock, Janet (FDA/CDER) <(b) (6)>; Young, John
(b) (6); Colvis, Christine (NIH/NCATS) [E] <(b) (6)>; Desrosiers, Betsy
(b) (6); Eric Hughes (b) (6); Jansen, Kathrin
(b) (6); Kurilla, Michael (NIH/NCATS) [E] (b) (6); Lowy, Douglas (NCI)
<(b) (6)>; Read, Sarah (NIH/NIAID) [E] <(b) (6)>; Young, John <(b) (6)>
Adam, Stacey (FNIH) [T] <(b) (6)>; Margaret Anderson (b) (6); Appell, Evan
(b) (6); Chen, Helen Q. (b) (6); Connelly, Sarah (b) (6)
Gonzalez, Nina <(b) (6)>; Hawk, Harrison (b) (6); Mendelson, Jesse
(b) (6); Menetski, Joseph (FNIH) [T] (b) (6); Nasr, Hana (b) (6)
Santos, Michael (FNIH) [T] (b) (6); Sorosa, Alex David (b) (6); Stratton, Benjamin
<(b) (6)>; btolman (b) (6); Tountas, Karen (FNIH) [T] <(b) (6)>
Wachtel, Jonathan <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)>; Austin, Christopher (NIH/NCATS) [E]
(b) (6); Burklow, John (NIH/OD) [E] <(b) (6)>; Carluccio, Dana

< (b) (6) Castillejos, Carlos < (b) (6) FNIH Central Account
(b) (6) >; Hallett, Adrienne (NIH/OD) [E] (b) (6) Lane, Cliff (NIH/NIAID) [E]
< (b) (6) Myles, Renate (NIH/OD) [E] (b) (6) Parker, Ashley (NIH/OD) [E]
(b) (6) ; Tabak, Lawrence (NIH/OD) [E] < (b) (6) Wolinetz, Carrie (NIH/OD) [E]
(b) (6) Meltzer, Abbey (FNIH) [T] (b) (6)

Subject: RE: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION

Dear ACTIV Leadership Team and meeting attendees:

Please see corrected version of materials. Sorry for the confusion.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 5:08 PM
To: Austin, Christopher (NIH/NCATS) [E] < (b) (6) Bancel, Stephane
< (b) (6) Carter, Kara < (b) (6) Cavaleri, Marco
(b) (6) ; Cihlar, Tomas (b) (6) ; Collins, Francis (NIH/OD) [E]
(b) (6) Corey, Larry < (b) (6) Culp, Michelle (NIH/OD) [E] (b) (6) ;
Victoria Davey (b) (6) >; Disbrow, Gary (OS/ASPR/BARDA) (b) (6) >; Dolsten, Mikael
< (b) (6) Erbeling, Emily (NIH/NIAID) [E] < (b) (6) >; Erck, Stan
< (b) (6) Fauci, Anthony (NIH/NIAID) [E] (b) (6) Freire, Maria (FNIH) [T]
(b) (6) >; Gadbois, Ellen (NIH/OD) [E] (b) (6) Gibbons, Gary (NIH/NHLBI) [E]
< (b) (6) Hudson, Thomas < (b) (6) James, Stephanie (FNIH) [T]
(b) (6) ; Johnson, Robert (OS/ASPR/BARDA) (b) (6) Kramer, Lynn
(b) (6) Lane, Cliff (NIH/NIAID) [E] (b) (6) ; Lepore, John (b) (6) ;
Marks, Peter (FDA/CBER) < (b) (6) Marston, Hilary (NIH/NIAID) [E] < (b) (6)
Mascola, John (NIH/VRC) [E] < (b) (6) Meeker, David < (b) (6) Menetski, Joseph
(FNIH) [T] <jmenetski@fnih.org>; Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6) Pandya, Hitesh
< (b) (6) Pangalos, Mene < (b) (6) Pao, William
< (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6) Paul, Steve < (b) (6)
Perlmutter, Roger (b) (6) >; Plenge, Robert (b) (6) ; Plump, Andy
(b) (6) >; Rachel Ramoni < (b) (6) Reed, John (b) (6) Reese,
David < (b) (6) Rouse, Doris < (b) (6) Santos, Michael (FNIH) [T] < (b) (6)
Skovronsky, Daniel (b) (6) Stein, Peter (FDA/CDER) < (b) (6) ; Stoffels, Paul
< (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Talley, Michael
(b) (6) >; Tsai, John < (b) (6) Vessey, Rupert < (b) (6) Virgin, Skip
(b) (6) >; Wholley, David (FNIH) [T] (b) (6) ; Woodcock, Janet (FDA/CDER)

< (b) (6) >; Young, John < (b) (6) Colvis, Christine (NIH/NCATS) [E]
 (b) (6) Desrosiers, Betsy (b) (6) ; Eric Hughes
 >; Jansen, Kathrin (b) (6) ; Kurilla, Michael (NIH/NCATS) [E]
 (b) (6) Lowy, Douglas (NCI) < (b) (6) ; Read, Sarah (NIH/NIAID) [E] (b) (6) ;
 Young, John < (b) (6) Adam, Stacey (FNIH) [T] (b) (6) Margaret Anderson
 < (b) (6) Appell, Evan (b) (6) ; Chen, Helen Q. < (b) (6)
 Connelly, Sarah (b) (6) >; Gonzalez, Nina (b) (6) . Hawk, Harrison
 (b) (6) >; Mendelson, Jesse (b) (6) ; Menetski, Joseph (FNIH) [T]
 Nasr, Hana < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) . Sorosa,
 Alex David (b) (6) Stratton, Benjamin (b) (6) >; btolman (b) (6) ;
 Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan (b) (6) ; Wholley, David (FNIH) [T]
 < (b) (6)
Cc: Anderson, James (NIH/OD) [E] (b) (6) Austin, Christopher (NIH/NCATS) [E]
 (b) (6) ; Burklow, John (NIH/OD) [E] < (b) (6) Carluccio, Dana
 < (b) (6) Castillejos, Carlos < (b) (6) FNIH Central Account
 (b) (6) >; Hallett, Adrienne (NIH/OD) [E] (b) (6) Lane, Cliff (NIH/NIAID) [E]
 (b) (6) Myles, Renate (NIH/OD) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E]
 < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Wolinetz, Carrie (NIH/OD) [E]
 (b) (6) >; Meltzer, Abbey (FNIH) [T] (b) (6)

Subject: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, December 16, 10:00 – 11:30 a.m. Eastern U.S. Time**. The minutes from the November 19 Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/12/2020 5:50:01 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Butterson, Joan (b) (6)]; De Claro, R. Angelo (FDA/CDER) [(b) (6) Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Hughes, Eric [(b) (6) Judy Currier (b) (6) Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W (b) (6)]; Menon, Sandeep [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Shen, Yuan Li (FDA/CDER) [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6) Collins, Sylva (FDA/CDER) [(b) (6)]
CC: Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6)]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Wachtel, Jonathan (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Gonzalez, Nina [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas Smalldon [(b) (6)]
Subject: ACTIV Therapeutics-Clinical Working Group Meeting #2
Attachments: ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 1_Key Takeaways_04152020v2.docx; ACTIVPrioritizationCriteria-v2.xlsx; 2020-04-14 TX-Clinical_WG_Agent_Prioritization_Subgroup_Summary.pdf; ACTIV Therapeutics-Clinical WG Meeting Agenda_04152020.pdf; ACTIV Therapeutics-Clinical WG 16Apr2020 Meeting Guide 04152020.pdf
Location: <https://zoom.us/> (b) (6)
Start: 4/16/2020 4:00:00 PM
End: 4/16/2020 5:30:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier, Kim, Elizabeth, LaVange, Lisa; Levy, Elliot, Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER)
Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Doug as (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Rose Li; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon

Dear COVID PPP Therapeutics-Clinical WG Members and Co-Chairs from other WGs,

Thank you all for all your hard work this week. We cannot thank you enough for your time and dedication to this important effort. Today's large group meeting will serve for the two subgroups to come back together and provide updates to each other and ensure we are staying on a unified path to move forward for this workstream.

Please find attached the materials for today's meeting:

1. Agenda
2. Slides for the presentation
3. Formal summary for Agent Prioritization Subgroup – 1st Meeting
4. Draft Agent Prioritization Criteria/Data Needed (Excel Sheet)
5. High Level summary and action items for the Master Protocol Subgroup – 1st Meeting

Note: The Master Protocol Subgroup will be having a second meeting immediately before this meeting, so we may be updating their summary slides on the fly during the meeting. Thank you for your patience and understanding with this fast moving process.

Reminder #1: If you are part of the Agent Prioritization Subgroup, we would like your feedback on the criteria in the Excel Spreadsheet attached.

Reminder #2: If you have not already done so, please fill out this Doodle Poll with your availability.

<https://doodle.com/poll/nhd5zgimn537cggk5>

Agent Prioritization Subgroup we especially need you to fill out for tomorrow as soon as you can.

If you have any questions, please do not hesitate to reach out.

Kind regards,

Stacey, on Behalf of the TX-Clinical WG

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From: John Lepore (b) (6)
Sent: 4/9/2020 12:38:28 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: URGENT: Invitation to join the Vaccines Working Group of the COVID PPP

Dear Francis -

Thank you very much for sponsoring this critical initiative and for enabling GSK to contribute.

Please do reach out if you see any other way we could be of help.

With best wishes -

John

John Lepore
SVP, Head of Research

GSK
1250 S. Collegeville Road, Mail Code UP4-4400, Collegeville, PA 19426, US
Email (b) (6)
Tel (b) (6)
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From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, April 08, 2020 8:27 PM
To: Emmanuel Hanon <(b) (6)>
Cc: Melencio, Cheryl (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> John Lepore <(b) (6)>
Subject: URGENT: Invitation to join the Vaccines Working Group of the COVID PPP

EXTERNAL

Dear Dr. Hanon,

Addressing the COVID 19 pandemic is an urgent priority for the entire biomedical research community. Appropriately, the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond. But there is still no proven treatment, and safe and effective vaccines are many months away.

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and a vaccine candidate. But given the seriousness of this global public health crisis, it is time to broaden the response and create a focused public-private partnership with FDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics. This past Friday I led an initial discussion convened by the Foundation for the National Institutes of Health (FNIH) to decide on the initial research agenda for the partnership. There was broad support from all sectors for this model — with some harkening back to a similar partnership that led to the development of antivirals for HIV/AIDS many years ago. Inspired by the shared embrace of a call to action, we are immediately launching efforts to collaborate in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development. Those four areas, and a summary of the meeting, are described in the attached document.

Each area will be powered by a nimble Working Group that includes appropriate domain expertise drawn from among our stakeholders. **You have been recommended to us by John Lepore as a member of the Vaccines Working Group.** The primary objective of this working group is to provide a collaborative framework for advancing vaccine development. I expect this will require a significant investment of your time when I know time is scarce. But these very serious circumstances call for full dedication to action from us all. I am personally committed to doing everything possible to support the execution of this partnership, and would be deeply appreciative if you will contribute your talents to this important effort.

Please direct your response to this invitation by Thursday April 9 (tomorrow! sorry this is such short notice) at 12pm EDT to Cheryl Melencio (b) (6). You may send any questions to Mike Santos (b) (6) at FNIH. A calendar invitation to the initial meeting of the Working Group will be sent out shortly after the response deadline.

I look forward to working with you on this critical effort.

Best,
Francis S. Collins, M.D., Ph.D.
Director, NIH

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)], Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Na mish Patel [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)] Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]
CC: Elizabeth Kim [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski]; Alvarez, Rosa Maria [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: UK Therapeutics Prioritization List and Process
Attachments: XYZ candidate agent list as of 4-15-20.xlsx; ACCORD product selection process 4-15-20 deid.pptx

Dear ACTIV TX-Clinical Agent Prioritization Subgroup Members,

Please see attached a slightly anonymized list of therapeutics considered by the science group in the UK that we spoke about. They have indicated their permission for us to share this with this group only, to aid in your deliberations about our parallel agent prioritization efforts, but with the express request that you not copy or distribute this beyond the group on this email. We have been asked to emphasize that this is a work in progress and does not represent the end of a considered or consolidated process, nor has that process or these results been formally adopted or endorsed by any UK government agency or organization. We will work with Deloitte to incorporate such information as you think valuable into the larger inventory of potential agents for prioritization that we have been working on with you, by the way.

FYI, we have asked for an update on the protocol that would be associated with testing such agents as may be selected, and have been told that it is not sufficiently finalized to be shared yet. We will let you and the MP Subgroup know when we have something to share there.

Thank you all for your help in adhering to our collaboration guidelines from that team.

Kind regards,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) Mobile: (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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| (b) (6) LaVange, Lisa M | (b) (6) Sandeep Menon
| (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham];
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B.
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John
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| (b) (6) (b) (6) (b) (6) (b) (6)
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(b) (6) Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna
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Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Kozak, Marina
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CC: Demarcus | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
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| (b) (6) Eron, Joseph J Jr (b) (6) Smith, David
| (b) (6) Paul Klekotka | (b) (6) Ajay Nirula | (b) (6) Chen,
Helen Q. | (b) (6)
Subject: HOLD for Potential ACTIV-2 Writing Team Meeting - Review of FDA Comments
Location: <https://fnih.zoom.us>. (b) (6)
Start: 6/18/2020 3:00:00 PM
End: 6/18/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange, Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price;
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna;
(b) (6) Kim, Peter (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa;
Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
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US (San Jose)

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Password (b) (6)

Find your local number: <https://fnih.zoom.us/j/a> (b) (6)

Sent: 8/3/2020 2:36:38 PM
Subject: FW: Notes from Wednesday's ACTIV Leadership Team Meeting
Attachments: 2020-07-29_ACTIV_Leadership_Team_Meeting_Summary final.docx

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Saturday, August 1, 2020 4:41 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane
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<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]
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Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael <(b) (6)> Erbeling,
Emily (NIH/NIAID) [E] <(b) (6)> Erck, Stan <(b) (6)> Fauci, Anthony (NIH/NIAID) [E]
<(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gadbois, Ellen (NIH/OD) [E]
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Lepore, John <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary
(NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David
<(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Messonnier, Nancy
(CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh <(b) (6)> Pangalos, Mene
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Young, John <(b) (6)>
Cc: Bianchi, Diana (NIH/NICHD) [E] <(b) (6)> Byrnes, Noni (NIH/CSR) [E] <(b) (6)> G ass,
Roger (NIH/FIC) [E] <(b) (6)> Hodes, Richard (NIH/NIA) [E] <(b) (6)> Koob, George
(NIH/NIAAA) [E] <(b) (6)> Koroshetz, Walter (NIH/NINDS) [E] <(b) (6)> Langevin,
Helene (NIH/NCCIH) [E] <(b) (6)> Norris, Andrea (NIH/CIT) [E] <(b) (6)> Perez-
Stable, Eliseo (NIH/NIMHD) [E] <(b) (6)> Rodgers, Griffin (NIH/NIDDK) [E]
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Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Myles,
Renate (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Gorman, Greta
(FNIH) [T] <(b) (6)> Meltzer, Abbey (FNIH) [T] <(b) (6)>
Subject: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear All:

Please see the notes from our teleconference on Wednesday, July 29. The action items are listed at the top of the document. Please let me know any additional comments or questions regarding these notes.

Thank you again for all your support of and contributions to ACTIV.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNHI earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
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CC: Diamond, Michael [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa72428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6)]; Hughes, Eric [(b) (6)]; Jansen, Kathryn [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4b79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
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Subject: RE: ACTIV Preclinical working group (Friday meeting)

Attachments: PRECLINICAL Working Group Agenda 20200522 d1.pptx; Animal Model Summaries.zip

Hi all,

Please find attached some materials to aid in our discussion today.

- * The first attachment contains the agenda as well as our WG's objectives and timeline.
- * The second attachment is a folder with the Animal Model 'one-pager' summaries.

Please let us know if you have any questions. Look forward to our discussion tomorrow.

Best,
Joe and Rosa

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:48 PM

To: (b) (6) Menetski, Joseph (FNIH) [T]; (b) (6) (b) (6) (b) (6)
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(b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)

Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter
(OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Tomas Cihlar, Qashu, Felicia (NIH/OD) [E]
Cc: Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];
Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E];
Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey
(FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan;
Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E];
Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Lowy,
Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Louise Pitt (b) (6) Pitt, Margaret L CIV USARMY
MEDCOM USAMRIID (USA); Nancy Haigwood; Gadbois, Ellen (NIH/OD) [E]; Hild, Sheri (NIH/OD) [E]

Subject: ACTIV Preclinical working group (Friday meeting)

When: Friday, May 22, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom>. (b) (6)

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Sent: 4/14/2020 1:54:16 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner | (b) (6) Keith Gottesdiener | (b) (6) Eric Hughes
| (b) (6) LaVange, Lisa M | (b) (6) Elliott Levy | (b) (6) Sandeep Menon | (b) (6) Amanda Peppercorn | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn | (b) (6)
CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rose Li Central Account (b) (6) Lucas Smalldon | (b) (6) Butcher, Tina | (b) (6)
Subject: ACTIV TX-Clinical WG Master Protocol Subgroup -1st Meeting

Dear ACTIV Therapeutics-Clinical WG,

Thank you for your interest and participation in the Master Protocol sub-group. We are appreciative of your time and look forward to a focused discussion on the development of COVID-19 Master Protocols.

Our first meeting will take place today, **Wednesday April 15th** from **1:30pm-2:30pm ET**. Dial-in instructions are below, similar to the zoom call on Monday. We wanted to notify you promptly of the meeting time and will follow up with an agenda and any necessary materials prior to the call.

Please note that this is not a fixed timeslot for upcoming sub-group meetings. After this first sub-group meeting, we will send out a scheduling link to coordinate the best time for sub group meetings moving forward.

Kind regards,
Stacey, on behalf of the ACTIV TX-Clinical WG

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Stacey J. Adam, PhD

Director, Cancer

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Sent: 6/18/2020 9:42:07 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesdener, Keith
(b) (6) Hughes, Eric | (b) (6) Judy Currier
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike
| (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn | (b) (6) Garner, Carl | (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisei]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner | (b) (6)

CC. Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6)]; Jansen, Kathrin [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6)]; Biggs, Mary [(b) (6)]; Butcher, Tina [(b) (6)]; Demarcus [(b) (6)]; Macone, Erin [(b) (6)]; Melenc o, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [(b) (6)]; Tolman, Brett [(b) (6)]; Alvarez, Rosa [(b) (6)]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6)]; Rose Li Central Account [(b) (6)]; Anderson, Margaret [(b) (6)]; Lucas Smalldon [(b) (6)]; Stratton, Benjamin [(b) (6)]; Mollica, Linda /US [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [(b) (6)]; Wung, Peter /US [(b) (6)]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]

Subject: Initia Follow-up from ACTIV TX-Clinical Working Group Meeting #11

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200618.pdf

Dear ACTIV TX-Clinical Working Group,

Please find attached the slides from our meeting today. I will also follow up with a formal summary tomorrow.

Thanks,
Stacey

Stacey J. Adam, PhD
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Sent: 5/29/2020 5:58:38 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
 - OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
 - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
 - ACTIV hiVIG (sponsored by NIAID) - in progress
 - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
 - ACTIV-2* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) - projected launch June
 - ACTIV-3* – Neutralizing Monoclonal Antibodies inpatient Master Protocol (NIAID NSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/II) – projected launch July
 - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) – (Phase II/III) – projected launch late June
 - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (if needed; i.e. if agents are not incorporated into mAb protocols)
* current priority
- [for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
 - Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup
 - Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
 - ACTIV-1 Protocol for immunomodulators
 - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)

- 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
- All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
- Phase III master protocol design for ACTIV-1 includes aggressive efficacy and safety assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
- Companies have agreed to share data + common control arm + common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
- Protocol is 80% complete
 - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
 - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
 - All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- “ACTIV-4” Protocol for anticoagulants
 - Need bullets from NHLBI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
 Senior Vice-President, Research Partnerships
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Subject: Fwd: ACTIV Leadership/EC Call #12
Attachments: 2021-01-14_ACTIV_Leadership_Team_and_Executive_Committee_Meeting_Summary_vF.pdf; ATT00001.htm

FYI

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: (b) (6)

Begin forwarded message:

From: "Wholley, David (FNIH) [T]" <(b) (6)>
Date: January 17, 2021 at 12:18:46 PM EST
To: "Melencio, Cheryl (FNIH) [T]" <(b) (6)> "Austin, Christopher (NIH/NCATS) [E]" <(b) (6)> "Carter, Kara" (b) (6) >, "Cavalieri, Marco" <(b) (6)> "Cihlar, Tomas" <(b) (6)> "Collins, Francis (NIH/OD) [E]" <(b) (6)> "Corey, Larry" <(b) (6)> "Culp, Michelle (NIH/OD) [E]" <(b) (6)> Victoria Davey <(b) (6)> "Disbrow, Gary (OS/ASPR/BARDA)" <(b) (6)> "Dolsten, Mikael" <(b) (6)> "Erbelding, Emily (NIH/NIAID) [E]" <(b) (6)> "Erck, Stan" <(b) (6)> "Gadbois, Ellen (NIH/OD) [E]" <(b) (6)> "Gibbons, Gary (NIH/NHLBI) [E]" <(b) (6)> >, "Hudson, Thomas" <(b) (6)> "James, Stephanie (FNIH) [T]" <(b) (6)> "Johnson, Robert (OS/ASPR/BARDA)" <(b) (6)> "Kramer, Lynn" <lynn (b) (6)> "Lanc, Cliff (NIH/NIAID) [E]" <(b) (6)> "Marks, Peter (FDA/CBER)" <(b) (6)> "Marston, Hilary (NIH/NIAID) [E]" <(b) (6)> "Mascola, John (NIH/VRC) [E]" <(b) (6)> "Mecker, David" <(b) (6)> "Menetski, Joseph (FNIH) [T]" <(b) (6)> "Messonnier, Nancy (CDC/DDID/NCIRD/OD)" <(b) (6)> "Pandya, Hitesh" <(b) (6)> "Pao, William" <(b) (6)> "Parker, Ashley (NIH/OD) [E]" <(b) (6)> "Perlmutter, Roger" <(b) (6)> "Plenge, Robert" <(b) (6)> "Plump, Andy" <(b) (6)> "Rouse, Doris" <(b) (6)> "Santos, Michael (FNIH) [T]" <(b) (6)> "Skovronsky, Daniel" <(b) (6)> "Stein, Peter (FDA/CDER)" <(b) (6)> "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)> "Talley, Michael" <(b) (6)> "Tsai, John" <(b) (6)> "Vessey, Rupert" <(b) (6)> >, "Virgin, Skip" (b) (6) >, "Woodcock, Janet (FDA/CDER)" <(b) (6)> >, "Young, John" (b) (6) "Colvis, Christine (NIH/NCATS) [E]" <(b) (6)> Eric Hughes <(b) (6)> "Jansen, Kathrin" <(b) (6)> "Kurilla, Michael (NIH/NCATS) [E]" <(b) (6)> "Lowy, Douglas (NCI)" <(b) (6)> "Read, Sarah (NIH/NIAID) [E]" <(b) (6)> "Adam, Stacey (FNIH) [T]" <(b) (6)> Margaret Anderson <(b) (6)> "Appell, Evan" <(b) (6)> "Chen, Helen" <(b) (6)> "Connelly, Sarah" <(b) (6)> "Gonzalez, Nina" <(b) (6)> "Hawk, Harrison"

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 (NIH/OD) [E]" < (b) (6) "Burklow, John (NIH/OD) [E]"
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 "Castillejos, Carlos" < (b) (6) FNIH Central Account
 < (b) (6) "Hallett, Adrienne (NIH/OD) [E]" < (b) (6)
 "Myles, Renate (NIH/OD) [E]" < (b) (6) "Wolinetz, Carrie (NIH/OD) [E]"
 < (b) (6) "Meltzer, Abbey (FNIH) [T]" < (b) (6) "Esser, Mark"
 (b) (6) >, "Bancel, Stephane" (b) (6)
 "Fauci, Anthony (NIH/NIAID) [E]" < (b) (6) "Lepore, John"
 <john.i.lepore@gsk.com>, "Pangalos, Menc" < (b) (6) "Paul, Steve"
 < (b) (6) Rachel Ramoni < (b) (6) "Reed, John"
 < (b) (6) "Reese, David" < (b) (6) "Stoffels, Paul"
 < (b) (6) "Desrosiers, Betsy" <elizabeth (b) (6)
 Cc: "Austin, Sarah (NIH/NIAID) [E]" < (b) (6) "Barasch, Kimberly
 (NIH/NIAID) [C]" < (b) (6) "Burrus-Shaw, Cyndi (NIH/OD) [E]"
 < (b) (6) "Carver, Trea (NIH) [C]" < (b) (6) "Caulfied,
 Anita" < (b) (6) "Coan, Amanda" < (b) (6) "Conrad,
 Patricia (NIH/NIAID) [E]" < (b) (6) "Dimishkov, Roxanne (NIH/NHLBI)
 [C]" < (b) (6) "Edl, Susan" < (b) (6) "Fuhrer, Nicole"
 <nicole.fuhrer@novartis.com>, "Giorgi, Sara" < (b) (6) "Hoffstetter,
 Renata (FNIH) [T]" < (b) (6) "Iberdemaj, Vaide"
 < (b) (6) "Jenkins, Christine S." <christine (b) (6)
 "Lagos, Enrique (NIH/NCATS) [E]" < (b) (6) "Lever, Susan"
 < (b) (6) "Martin, Melisa" < (b) (6) "McManus, Ayanna
 (NIH/OD) [E]" < (b) (6) "Minnich, Beth" <bminnich@fredhutch.org>,
 "Perala, Mie" < (b) (6) "Protasiewicz, Ann" < (b) (6)
 "Riccobene, Kim" < (b) (6) "Riggin, Mary" < (b) (6) "Ripley,
 Nadege" < (b) (6) "Schuster, Donna" < (b) (6)
 "Sepulveda, Dorina (FNIH) [T]" < (b) (6) "Simon, Dina (NIH/OD) [C]"
 < (b) (6) "Suhana, Tina (NIH/VRC) [E]" < (b) (6) "Thomas,
 Ashley (FDA/CDER)" < (b) (6) , "Wood, Gretchen (NIH/OD) [E]"
 < (b) (6) "Togashi, Micko (NIH/NCI) [E]" < (b) (6)
 "Underwood, Nancy" <nancy (b) (6) "Zottoli, Jessica"
 < (b) (6) "Hughes, Karen (NIH/OD) [E]" < (b) (6)
 "Tajalli, Ada (NIH/OD) [E]" < (b) (6) "Regan, Donna M"
 < (b) (6) "Magbie-Robinson, Kim (NIH/OD) [C]" (b) (6)
 "Vessey, Rupert" < (b) (6) "Lowy, Douglas
 (NIH/NCI) [E]" < (b) (6) "Lumsden, Joanne (NIH/NCATS) [C]"
 < (b) (6) "Ellis, Carol" < (b) (6) "Bell, Julie"
 < (b) (6) "Hoban, Michelle" < (b) (6) "Melencio, Cheryl
 (FNIH) [T]" < (b) (6)

Subject: RE: ACTIV Leadership/EC Call #12

Dear ACTIV Executive Committee and Leadership Team members, and meeting attendees:

Attached please see the minutes from our meeting this past Thursday, January 14, 2021. As always please let me know if you have any additional comments or questions.

Regards,
David Wholley

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:24:07 PM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Na mish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; (b) (6) (b) (6) (b) (6)
Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12
Location: <https://fnih.zoom.us/> (b) (6)
Start: 5/21/2020 3:00:00 PM
End: 5/21/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors, Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) (b) (6) (b) (6)
Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] (b) (6)

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US (Germantown)

US (San Jose)

US (San Jose)

US (Tacoma)

US (Houston)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/> (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/22/2020 12:52:44 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner | (b) (6) Keith Gottesdiener | (b) (6) Eric Hughes | (b) (6) LaVange, Lisa M | (b) (6) Elliott Levy | (b) (6) Sandeep Menon | (b) (6) Amanda Peppercorn | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn | (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael | (b) (6)
CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan | (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [Peter].
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7
Location: <https://nih.zoom.> (b) (6)
Start: 4/24/2020 2:00:00 PM
End: 4/24/2020 3:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylvia (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael

Optional Attendees: Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley
(NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

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US
US
US (Houston)

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Find your local number: <https://fnih.zoom.us/>, (b) (6)

From: Bozzette, Sam (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85F05A3619CF47C7AE39D7BCF0AAC88D-BOZZETTESAA]
Sent: 10/16/2020 9:52:34 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: 1st ACTIV-1 patient has been randomized

My partner saw it - she said that you were very good!

From: "Collins, Francis (NIH/OD) [E]" (b) (6)
Date: Friday, October 16, 2020 at 5:45:38 PM
To: "Bozzette, Sam (NIH/NCATS) [E]" (b) (6) >, "Boucher, Cynthia (NIH/NCATS) [E]" < (b) (6) >, "Chang, Soju (NIH/NCATS) [E]" (b) (6) >, "Atkinson, Jane (NIH/NCATS) [E]" < (b) (6) >, "Gavin, Brian" < (b) (6) >, "Sadeh, Jonathan" < (b) (6) >, "Melsheimer, Rich [CNTNL]" (b) (6) >, "Beumont-Mauviel, Maria [JRDUS]" (b) (6) >, "Bharucha_David" < (b) (6) >, "Ferguson_William" < (b) (6) >, "Eric Hughes" < (b) (6) >, "Read, Sarah (NIH/NIAID) [E]" (b) (6) >, "LaVange, Lisa M" < (b) (6) >, "Proschan, Michael (NIH/NIAID) [E]" < (b) (6) >, "Gardner, Bobbi (NIH/NCATS) [E]" < (b) (6) >, "Sandeep Menon" < (b) (6) >, "Yong, Florence H" < (b) (6) >, "Trank, Christina" < (b) (6) >, "Moyo, Vusi" < (b) (6) >, "Kimmel, Bridget [JRDUS]" (b) (6) >, "Adam, Stacey (FNIH) [T]" < (b) (6) >, "Marti, Emily (NIH/NCATS) [E]" < (b) (6) >, "Eisnor, Derek (OS/ASPR/BARDA)" < (b) (6) >, "Austin, Christopher (NIH/NCATS) [E]" < (b) (6) >, "Woodcock, Janet (FDA/CDER)" < (b) (6) >, "Mason, Robin (OS/ASPR/BARDA)" < (b) (6) >, "O'Sullivan_Alexandra" < (b) (6) >, "Montgomery, Stephanie" < (b) (6) >, "Stock, Thomas (HHS/IOS)" < (b) (6) >, "Neta Nelson" < (b) (6) >, "Butler, Sandy" < (b) (6) >, "Daniel Benjamin Jr, M.D., Ph.D." < (b) (6) >, "Theresa Jasion" < (b) (6) >, "Molina, Daniel" < (b) (6) >, "Rose Beci" < (b) (6) >, "Lind, Brian (NIH/NCATS) [E]" < (b) (6) >, "Mason, Robin (OS/ASPR/BARDA)" < (b) (6) >, "O'rourke, Anna (OS/ASPR/BARDA) (CTR)" < (b) (6) >, "Austin, Christopher (NIH/NCATS) [E]" < (b) (6) >, "Lori Hudson, Ph.D." < (b) (6) >, "Huyen Cao" < (b) (6) >, "Huyen Cao" < (b) (6) >, "Brody, Betty (OS/ASPR/BARDA)" < (b) (6) >, "Chiang, Anna (OS/ASPR/BARDA)" < (b) (6) >, "Schmidt, Jeffrey (OS/ASPR/BARDA)" < (b) (6) >
Subject: RE: 1st ACTIV-1 patient has been randomized

Terrific! I just talked about the study with Wolf Blitzer on CNN – it's great to have it underway.

Many thanks to all who worked so hard to get to this point. Onward!

Francis

From: Bozzette, Sam (NIH/NCATS) [E] < (b) (6) >
Sent: Friday, October 16, 2020 4:48 PM
To: Boucher, Cynthia (NIH/NCATS) [E] < (b) (6) > Atkinson, Jane (NIH/NCATS) [E]

< (b) (6) Chang, Soju (NIH/NCATS) [E] < (b) (6) ' (b) (6)
 < (b) (6) 'Gavin, Brian' < (b) (6) 'Sadeh, Jonathan' < (b) (6)
 'Melsheimer, Rich [CNTNL]' < (b) (6) 'Beumont-Mauviel, Maria [JRDUS]' < (b) (6)
 'Bharucha_David' < (b) (6) 'Ferguson_William' < (b) (6) Eric Hughes
 < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) 'LaVange, Lisa M'
 < (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Gardner, Bobbi (NIH/NCATS) [E]
 < (b) (6) 'Sandeep Menon' < (b) (6) 'Yong, Florence H'
 < (b) (6) 'Trank, Christina' < (b) (6) 'Moyo, Vusi'
 < (b) (6) Collins, Francis (NIH/OD) [E] < (b) (6) 'Kimmel, Bridget [JRDUS]
 < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Marti, Emily (NIH/NCATS) [E]
 < (b) (6) Eisnor, Derek (OS/ASPR/BARDA) < (b) (6) ' (b) (6)
 < (b) (6) Austin, Christopher (NIH/NCATS) [E] < (b) (6) Collins, Francis (NIH/OD) [E]
 < (b) (6) Woodcock, Janet (FDA/CDER) < (b) (6) Mason, Robin (OS/ASPR/BARDA)
 < (b) (6)
 Cc: 'Montgomery, Stephanie' < (b) (6) O'Sullivan_Alexandra
 < (b) (6) Stock, Thomas (HHS/IOS) < (b) (6) Neta Nelson
 < (b) (6) Butler, Sandy < (b) (6) Daniel Benjamin Jr, M.D., Ph.D.
 < (b) (6) Theresa Jasion < (b) (6) Molina, Daniel < (b) (6)
 Rose Beci < (b) (6) Lind, Brian (NIH/NCATS) [E] < (b) (6) Mason, Robin (OS/ASPR/BARDA)
 < (b) (6) O'rourke, Anna (OS/ASPR/BARDA) (CTR) < Anna. (b) (6) Austin, Christopher
 (NIH/NCATS) [E] < (b) (6) Lori Hudson, Ph.D. < (b) (6) "Huyen Cao"
 < (b) (6) <"Huyen Cao" < (b) (6) Huyen Cao < (b) (6) Brody, Betty
 (OS/ASPR/BARDA) < (b) (6) Chiang, Anna (OS/ASPR/BARDA) < (b) (6) Schmidt, Jeffrey
 (OS/ASPR/BARDA) < (b) (6)

Subject: 1st ACTIV-1 patient has been randomized

Hello.

The first patient has been randomized into ACTIV-1. Congratulations to all, especially Bill Powderly, Jane O'Halloran, and the rest of the Wash U team.

Happy weekend to all!

Sam B

Sam Bozzette, MD, PhD

Chief Medical Officer

Immediate Office of the Director

National Center for Advancing Translational Sciences

National Institutes of Health

6701 Democracy Blvd., Room 926

Bethesda, MD 20892

(Use ZIP code 20817 for overnight mail or courier)

Phone: (b) (6)

E-mail: (b) (6)

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/27/2021 10:48:43 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: FW: COLCORONA manuscript online

We heard the skepticism loud and clear on the ACTIV-2/3 Trial Oversight Committee call, fyi.

From: Adam, Stacey (FNIH) [T] < (b) (6) >
Sent: Wednesday, January 27, 2021 5:36 PM
To: Wholley, David (FNIH) [T] < (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) > Freire, Maria (FNIH) [T] < (b) (6) >
Subject: FW: COLCORONA manuscript online

Hi All,

FYI, COLOCORONA results...still a little skeptical.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Jonathan Arm < (b) (6) >
Sent: Wednesday, January 27, 2021 1:31 PM
To: Trevor Mundel < (b) (6) >; Chris Karp < (b) (6) > Dan Hartman < (b) (6) > Susan Hershenson < (b) (6) >; Dennis Lee < (b) (6) > Steven Kern < (b) (6) > Thea Norman < (b) (6) >
< (b) (6) > Ian Hudson < (b) (6) > Lynda, Stuart < (b) (6) >
< (b) (6) >; Ken Duncan < (b) (6) > Mike Poole < (b) (6) >
< (b) (6) > Robin Mogg < (b) (6) > Brad Wilken < (b) (6) > Scott Miller < (b) (6) >
< (b) (6) > Murray Lumpkin < (b) (6) > >; Peter Dull < (b) (6) >; Jared Silverman < (b) (6) >
< (b) (6) >; Jintanat Ananworanich < (b) (6) >; Penny Heaton < (b) (6) >
< (b) (6) > Mike Dunne < (b) (6) >; Nathalie Strub-Wourgaft < (b) (6) >
< (b) (6) >; Adam, Stacey (FNIH) [T] < (b) (6) >; Farhad Imam < (b) (6) >
Valerie Mizrahi < (b) (6) >; < (b) (6) >; Dr. Gagandeep Kang < (b) (6) >
< (b) (6) > < (b) (6) > Susan Fisher < (b) (6) >
< (b) (6) > Ramnik Xavier < (b) (6) > Souleymane Mboup < (b) (6) >
< (b) (6) >; < (b) (6) > RXAVI < (b) (6) >
Subject: FW: COLCORONA manuscript online

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From: Chen, Helen Q. | (b) (6)
Sent: 9/9/2020 5:27:15 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesd ener, Keith | (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn | (b) (6) Garner, Carl | (b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8f8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisei]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner

(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel], Phillips, L Revell CIV DTRA RD (USA) | (b) (6) Petrovick, Martha - 0449 - MITLL | (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]
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 Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting
 Attachments: DRAFT ACTIV Checkerboard 9.4.20.pdf

Dear ACTIV TX-Clinical Working Group Members,

As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH supported COVID 19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared more broadly once the information within it is public.

We would appreciate your review of this draft version of the table, which we are sharing ahead of tomorrow's Working Group meeting. Please do not share the table or the information in it further. We are looking forward to your input.

Warm regards,
Stacey, Mike, and Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] <(b)(6)>
Sent: Wednesday, June 17, 2020 8:48 AM
To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beidel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITL; (b)(6) Sizemore, Christine (NIH/FIC) [E]
Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b)(6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, September 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom>. (b)(6)

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Sent: 4/24/2020 11:29:47 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Butterton, Joan [(b) (6) Collins, Sylva (FDA/CDER) [(b) (6) Judy Currier [(b) (6)]; De Claro, R. Angelo (FDA/CDER) [(b) (6)]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [(b) (6) Rubin, Daniel B. (FDA/CDER) [(b) (6) Shen, Yuan Li (FDA/CDER) [(b) (6) Farley, John (FDA/CDER) [(b) (6) Goff, David (NIH/NHLBI) [E] [(b) (6) Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6) m]; Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6)
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #13
Location: <https://fnih.zoom.us/j> (b) (6)
Start: 5/1/2020 3:00:00 PM
End: 5/1/2020 4:00:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes, Lisa LaVange, Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E], Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER), Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US
Optional Attendees: Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/21/2020 4:54:26 PM
To: Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; (b) (6); Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter Adams]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6); (b) (6); (b) (6); (b) (6); (b) (6); Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6); Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6); (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rao, Srinivas [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6)]
CC: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6)]; Hughes, Eric [(b) (6)]; Jansen, Kathryn [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6)]; Kim, Elizabeth [(b) (6)]; Tolman, Brett [(b) (6)]; Wachtel, Jonathan [(b) (6)]; Prabhavathi Fernandes [(b) (6)]; Diamond, Michael [(b) (6)]; Rose Li [(b) (6)]; Dana Carluccio [(b) (6)]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwood.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Attachments: 2020-05-20 Preclinical WG Summary F1.docx

Dear Preclinical Working group members and attendees,

Please find the minutes from yesterday's meeting attached. Thank you for a very interesting meeting and all of the work you continue to do for the ACTIV effort.

Best regards,
Joe and Rosa

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

To: (b) (6) (b) (6) (b) (6) (b) (6)
Adams, Peter (OS/ASPR/BARDA); Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Menetski, Joseph (FNIH) [T]; (b) (6) (b) (6) (b) (6) (b) (6)
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(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)

Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar
Cc: Simon, Dina (NIH/OD) [C]; Florence, Clint (NIH/NCATS) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NCATS) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes, Diamond, Michael; Rose Li; Dana Carluccio, Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina, Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C, Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Wednesday, May 20, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://fnih.zoom> (b) (6)

Meeting ID: (b) (6)

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One tap mobile

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Dial by your location

(b) (6)

JS (Germantown)

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JS (San Jose)

JS (Tacoma)

JS (Houston)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6) |

From: (b) (6) | (b) (6)
Sent: 5/29/2020 10:44:42 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: Re: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Yes, she is waiting to see the draft ppts and will advise on the strategy then.

Sent from my iPhone

On May 29, 2020, at 6:06 PM, Freire, Maria (FNIH) [T] < (b) (6) > wrote:

Francis - have you had a chance to chat with Janet to coordinate messages? She is critical - in her low-key way, she is able to carry a huge part of the load. Moncef knows she has a rock-solid reputation with industry folks. And, of course, she was the one who asked for the money. M.

On May 29, 2020, at 5:59 PM, Collins, Francis (NIH/OD) [E] < (b) (6) > wrote:

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note - has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

From: Wholley, David (FNIH) [T] < (b) (6) >
Sent: Friday, May 29, 2020 1:59 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Cc: Adam, Stacey (FNIH) [T] < (b) (6) > Freire, Maria (FNIH) [T] < (b) (6) > Gonzalez, Nina < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >
Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to

highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
 - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
 - ACTIV hiVIG (sponsored by NIAID) – in progress
 - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
 - ACTIV-2* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
 - ACTIV-3* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
 - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI NINDS “Master” Network) (Phase II/III) – projected launch late June
 - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (*if needed; i.e. if agents are not incorporated into mAb protocols*)
 - * current priority
 - [for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup]
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
 - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
 - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
 - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
 - Phase III master protocol design for ACTIV 1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
 - Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
 - Protocol is 80% complete
 - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
 - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)

- All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; r (b) (5)
- “ACTIV 4” Protocol for anticoagulants
 - Need bullets from NHBLI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the cl nical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
 Senior Vice-President, Research Partnerships
 Foundation for the National Institutes of Health
 (b) (6)

foi101g
 11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

<Responses to Qs re AC Clinical Trial Strategy 052920 final fsc.docx>

From: Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 12/22/2020 4:45:53 PM
To: Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieri]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
(b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth | (b) (6) | btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) |; Prabhavathi Fernandes | (b) (6) | Diamond, Michael | (b) (6) | Rose Li | (b) (6) | Dana Carluccio | (b) (6) | Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D | (b) (6) | Dave Frankowski | (b) (6) |; antoinette_baric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoonoh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; Gadbois, El en (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen | (b) (6) | (b) (6) | Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; (b) (6) | Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd | (b) (6) | (b) (6)

Subject: ACTIV Preclinical full working group

Location: <https://nih.zoom.us/j> (b) (6)

Start: 4/22/2020 2:00:00 PM

End: 4/22/2020 3:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6) (b) (6) ; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6) (b) (6)

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathryn; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Doug as (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li, Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D;

Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison, Mason, Stephen; (b) (6) Connelly, Sarah; (b) (6) Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Meeting ID: (b) (6)

Passcode (b) (6)

Find your local number: <https://fnih.zoom.us>

(b) (6)

From: Tountas Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 4/16/2020 3:45:44 PM
To: Bascles, Lionel [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)] Desrosiers, Betsy [(b) (6)] Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickens]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshov]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King]; Kurlla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)] Srinivasan, Badhri [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6)] Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6)] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)] Criffield, Robin [(b) (6)] Hamilton, Nancy [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [(b) (6)] Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)] Carluccio, Dana [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6)] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6)] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Wachtel, Jonathan [(b) (6)]
Subject: RE: Clinical Trial Capacity WG - meeting #1 summary

Apologies, attached is a cleaner version.
Karen

From: Tountas, Karen (FNIH) [T]

Sent: Thursday, April 16, 2020 6:10 AM

To: Bascles, Lionel <(b) (6)> Cohen, Myron <(b) (6)> Corey, Larry
<(b) (6)> Desrosiers, Betsy <(b) (6)> Dickens, Jim (NIH/NCATS) [C]
<(b) (6)> Doroshow, James (NIH/NCI) [E] <(b) (6)> Goff, David (NIH/NHLBI) [E]
<(b) (6)> King, James <(b) (6)> Kurilla, Mike <(b) (6)> Nayak, Seema (NIH/NIAID)
[E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Payton, Manzine
<(b) (6)> Resnansky, Laura <(b) (6)> Srinivasan, Badhri
<(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Vincent, Mike
<(b) (6)> Woodcock, Janet (FDA/CDER) <(b) (6)>
Cc: Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Hughes, Eric <(b) (6)> Jansen,
Kathrin <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E]
<(b) (6)> Young, John <(b) (6)> Criffield, Robin <(b) (6)>
Hamilton, Nancy <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Minnich, Beth
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Ashley (FDA/CDER) <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Anderson, Margaret
<(b) (6)> Carluccio, Dana <(b) (6)> Cheryl (FNIH) Melencio [T]
<(b) (6)> <(b) (6)> Gonzalez, Nina <(b) (6)> Heaton, Penny
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Menetski, Joseph (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) <(b) (6)> Tuveson, Nancy
<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Wachtel, Jonathan
<(b) (6)>

Subject: Clinical Trial Capacity WG - meeting #1 summary

Dear Clinical Trial Capacity Working Group colleagues,

Attached is a summary of meeting #1 of the Clinical Trial Capacity Working Group. It was a very good start to this effort; thank you to everyone for participating in this important initial discussion.

Looking forward to forming the subgroups and initiating detailed activities
Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

(b) (6) fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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(FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Baric, Ralph
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(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter
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(b) (6) (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] (b) (6) Colvis,
Christine (NIH/NCATS) [E] | (b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6)
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(b) (6) Rao, Srinivas | (b) (6) ; Tomas Cihlar
| (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) | (b) (6)
(b) (6) (b) (6) (b) (6) |

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
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 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Desrosiers Betsy
 | (b) (6) Jansen, Kathrin | (b) (6) Alvarez, Rosa Maria
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 | (b) (6) Rose Li | (b) (6) Dana Carluccio
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 | (b) (6) Stratton, Benjamin | (b) (6) Hawk, Harrison
 | (b) (6) Mason, Stephen | (b) (6) (b) (6)

Start: 9/9/2020 2:00:00 PM
End: 9/9/2020 3:00:00 PM

Recurrence: (none)

From: Patterson, Amy (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AFAD1CA74B3E449D8B4F3191D658B70F-PATTERSA]
Sent: 9/9/2020 7:15:55 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaa9e06ebd70-parkeras]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adams4]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Ashley,
Great! We already sent the updates to Helen.
All the Best,
Amy

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, September 9, 2020 3:01 PM
To: Patterson, Amy (NIH/NHLBI) [E] <(b) (6)>
Cc: Chen, Helen Q. <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Brodd, Lauren (NIH/OD) [E] <(b) (6)>
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Amy,

We are happy to include any additional trials NHLBI would like to be included. Chris Austin's team at NCATS sent a NIH wide data call (maybe 2 months ago) to request ICs submit planned and ongoing COVID-19 trials -- we used this collective information for the NIH trials.

The Tx clinical WG has requested to review after this was presented to the ACTIV leadership team 2 weeks ago. Stacey and Helen will collect all of the additions/edits and the OD team will make those changes. We will also continue to update the matrix as trials continue to launch.

Thanks,
Ashley

-----Original Message-----

From: Patterson, Amy (NIH/NHLBI) [E] <(b) (6)>
Sent: Wednesday, September 9, 2020 2:50 PM
To: Chen, Helen Q. <(b) (6)> ; Adam, Stacey (FNIH) [T] <(b) (6)> Bozzette, Sam (NIH/NCATS) [E] <(b) (6)> ; Butterson, Joan <(b) (6)> ; De Claro, R. Angelo (FDA/CDER) <(b) (6)> Draghia-Akli, Ruxandra <(b) (6)> Eisner, Mark <(b) (6)> Gottesdiener, Keith <(b) (6)> Eric Hughes <(b) (6)> Judy Currier <(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa <(b) (6)> Levv, Elliot <(b) (6)> Mellors, John W <(b) (6)> Menon, Sandeep <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> <ashlev. (b) (6)> Patel, Naimish <naimish.patel@sanofi.com>: Peppercorn, Amanda <(b) (6)> Poole, Mike <(b) (6)> Proschan, Michael <(b) (6)> <(b) (6)> ; Read, Sarah (NIH/NIAID) [E] <(b) (6)> ; Santos, Michael (FNIH) [T] <(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Buchman, Tim <(b) (6)> (OS/ASPR/BARDA) (CTR) <(b) (6)> Collins, Sylva (FDA/CDER) <(b) (6)> Higgs, Amanda Peppercorn <(b) (6)> Garner, Carl <(b) (6)> Koroshetz, Walter (NIH/NINDS) [E] <(b) (6)> Elizabeth (NIH/NIAID) [E] <(b) (6)> Timothy Burgess <(b) (6)> Reineck, Lora (NIH/NHLBI) [E] <(b) (6)> <(b) (6)> Agarwal, Neil (NIH/NHLBI) [E] <(b) (6)> ; Rosenber, Yves (NIH/NHLBI) [E] <(b) (6)> Goff, David (NIH/NHLBI) [E] <(b) (6)> ; Brown, Jeremy (NIH/NINDS) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)> Jacqueline Kirchner <(b) (6)> Phillips, L <(b) (6)> <(b) (6)> Beigel, John (NIH) [E] <(b) (6)> ; Petrovick, Martha - 0449 - MITLI <(b) (6)> ; Sizenore, Christine (NIH/FIC) [E] <(b) (6)> <(b) (6)> ; Colvis, Christine (NIH/NCATS) [E] <(b) (6)> ; Desrosiers, Betsy <(b) (6)> ; Jansen, Kathryn <kathr (b) (6)> ; Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> ; Lowy, Douglas (NCI) <(b) (6)> ; Young, John <(b) (6)> <(b) (6)> ; Biaoq, Mary <(b) (6)> ; Butcher, Tina <(b) (6)> ; Demarcus <(b) (6)> ; Macone, Erin <(b) (6)> ; Melencio, Cheryl (FNIH) [T] <(b) (6)>

(b) (6) Salathin, Carla (b) (6) : Tountas, Karen (FNIH) [T]
 < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) James, Stephanie (FNIH) [T]
 < (b) (6) Wachtel, Jonathan (b) (6) btolman < (b) (6) Alvarez,
 Rosa Maria < (b) (6) Gonzalez, Nina < (b) (6) Dana Carluccio
 (b) (6) ; Rose Li Central Account <FNIH@roseliassociates.com>; Margaret
 Anderson < (b) (6) Lucas Smalldon <Lucas.Smalldon@roseliassociates.com>; Stratton,
 Benjamin < (b) (6) Mollica, Linda /US
 < (b) (6) Oashu, Felicia (NIH/OD) [E] < (b) (6) Rubin, Daniel B.
 (FDA/CDER) < (b) (6) >; Marston, Hilary (NIH/NIAID) [E] < (b) (6) Wung,
 Peter /US < (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] < (b) (6) Groesch, Mary
 (NIH/NHLBI) [E] < (b) (6) Shipp, Allan (NIH/NHLBI) [E] < (b) (6) Kindzelski,
 Andrei (NIH/NHLBI) [E] < (b) (6) Hone, David M (Dave) CIV DTRA 19 (USA)
 < (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
 (b) (6) Freire, Maria (FNIH) [T] < (b) (6) Elsaied, Olivia
 < (b) (6) Appell, Evan < (b) (6)
 Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Helen,
 Thanks for developing this helpful chart. Two of the NHLBI trials are not on the chart - will try to send you the info later today.
 Amy

-----Original Message-----

From: Chen, Helen Q. < (b) (6)>
 Sent: Wednesday, September 9, 2020 1:27 PM
 To: Adam, Stacey (FNIH) [T] (b) (6) Bozzette, Sam (NIH/NCATS) [E] < (b) (6)
 Butterton, Joan <joan_butterton@merck.com>; De Claro, R. Angelo (FDA/CDER) < (b) (6)
 Drachia-Akli, Ruxandra < (b) (6) Eisner, Mark < (b) (6) Gottesdiener, Keith
 < (b) (6) Eric Hughes <eri (b) (6) Judy Currier
 < (b) (6) Kim, Elizabeth < (b) (6) LaVange, Lisa < (b) (6)
 Levv, Elliot < (b) (6) Mellors, John W < (b) (6) Menon, Sandeep
 < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Patel, Nainish
 < (b) (6) Peppercorn, Amanda <amanda (b) (6) Poole, Mike
 < (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah
 (NIH/NIAID) [E] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Shen, Yuan Li
 (FDA/CDER) < (b) (6) Stein, Peter (FDA/CDER) < (b) (6) Wholley, David
 (FNIH) [T] < (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) <T (b) (6) Collins, Sylva
 (FDA/CDER) < (b) (6) Amanda Peppercorn < (b) (6) Garner, Carl
 < (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) Koroshetz, Walter
 (NIH/NINDS) [E] < (b) (6) Timothy Burgess < (b) (6) Reineck, Lora
 (NIH/NHLBI) [E] < (b) (6) Adgarwal, Neil (NIH/NHLBI) [E] <neil (b) (6)
 Rosenber, Yves (NIH/NHLBI) [E] < (b) (6) Goff, David (NIH/NHLBI) [E]
 < (b) (6) Brown, Jeremy (NIH/NINDS) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E]
 < (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6) Jacqueline Kirchner
 < (b) (6) Beidel, John (NIH) [E] < (b) (6) Phillips, L
 Revell CIV DTRA RD (USA) < (b) (6) Petrovick, Martha 0449 MITLL
 < (b) (6) Sizemore, Christine (NIH/FIC) [E]
 < (b) (6)
 Cc: Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy
 < (b) (6) Jansen, Kathrin < (b) (6) >; Kurilla, Michael
 (NIH/NCATS) [E] <michael.kurilla@nih.gov>; Lowy, Douglas (NCI) < (b) (6) Young, John
 < (b) (6) Biggs, Mary < (b) (6) Butcher, Tina < (b) (6)
 Demarcus < (b) (6) Macone, Erin <eri (b) (6) Melencio, Cheryl (FNIH) [T]
 < (b) (6) Salathin, Carla (b) (6) Tountas, Karen (FNIH) [T]
 (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) James, Stephanie (FNIH) [T]
 < (b) (6) : Wachtel, Jonathan < (b) (6) btolman < (b) (6) Alvarez,
 Rosa Maria < (b) (6) Gonzalez, Nina < (b) (6) Dana Carluccio
 < (b) (6) >; Rose Li Central Account < (b) (6) Margaret
 : Lucas Smalldon < (b) (6) Stratton,
 < (b) (6) Oashu, Felicia (NIH/OD) [E] < (b) (6) Mollica, Linda /US
 (NIH/NHLBI) [E] < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Patterson, Amy
 Hilary (NIH/NIAID) [E] < (b) (6) Wung, Peter /JS < (b) (6) Marston,
 (NIH/NHLBI) [E] < (b) (6) Groesch, Mary (NIH/NHLBI) [E] < (b) (6) Hoots, W. Keith
 Allan (NIH/NHLBI) [E] < (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E]
 < (b) (6) Hone, David M (Dave) CIV DTRA 19 (USA) < (b) (6) Shipp,
 Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) < (b) (6) I>: Freire, Maria (FNIH)
 [T] < (b) (6) Elsaied, Olivia < (b) (6) Appell, Evan < (b) (6)
 Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical Working Group Members,

As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH-supported COVID-19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared more broadly once the information within it is public.

We would appreciate your review of this draft version of the table, which we are sharing ahead of tomorrow's Working Group meeting. Please do not share the table or the information in it further. We are looking forward to your input.

Warm regards,
Stacey, Mike, and Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] <(b)(6)>
Sent: Wednesday, June 17, 2020 8:48 AM
To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beidel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b)(6) Sizemore, Christine (NIH/FIC) [E]
Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; jennifer.j.palmer@pfizer.com; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, September 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us/>; (b)(6)

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
<https://fnih.zoom.us/> (b)(6)
Meeting ID: (b)(6)
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Find your local number: [https://fnih.zoom.us/j/\(b\)\(6\)](https://fnih.zoom.us/j/(b)(6)) This message (including any attachments) contains confidential information intended for a specific individual and purpose, and is protected by law. If you are not the intended recipient, you should delete this message and any disclosure, copying, or distribution of this message, or the taking of any action based on it, by you is strictly prohibited.

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-ME.ENCIOC]
Sent: 6/8/2020 9:04:42 PM
To: Takas, Therese | (b) (6)
CC: Brodd, Lauren (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanm]; Metzger, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]
Subject: Permission to List on ACTIV Website

Dear Ms. Takas,

Karen Tountas provided me your name as a new member of the CT Capacity Working Group for the ACTIV Project. Please let me know if we have your permission to list you on the website.

Please let us know if this is how you would like to be listed.

- Therese Takas
Director, Clinical Operations
AstraZeneca

Please reply to all on your response.

Thank you

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 10/10/2020 9:33:56 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: Roster of ACTIV Vaccines WG
Flag: Follow up

Hi Francis,

In case you were looking for the opposite of what I sent in my previous email, this is the list of WG members who are also on the Clinical Trials Sub-Group.

Thanks,
Mike

Name	Organization
Paula Annunziato	Merck
Larry Corey	Fred Hutch
Ann Arvin	Stanford
Beth Bell	UW
Marco Cavaleri	EMA
Emilio Emini	Gates
Gregory M. Glenn	Novavax
Marion Gruber	CBER/FDA
Peter Hotez	Baylor and Texas Children's
Kathrin Jansen	Pfizer
Doug Lowy	NCI/NIH
Peter Marks	CBER/FDA
John Mascola	VRC/NIH
Nelson Michael	WRAIR
Paul Offit	Penn/CHOP
Tal Zaks	Moderna

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Saturday, October 10, 2020 3:10 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Freire, Maria

(FNIH) [T] < (b) (6)

Subject: RE: Roster of ACTIV Vaccines WG

Hi Francis,

Sure, no problem. The list below is only the non-WG members of the Sub-Group.

Thanks,

Mike

Name	Organization
Myron Cohen	UNC
Elizabeth Desrosiers	Merck
Macaya Douoguih	J&J
Peter Dull	Gates
Emily Erbeling	NIAID/NIH
Peter Gilbert	SCHARP/UW
Paul Gillard	GSK
Bill Gruber	Pfizer
Sanjay Gurunathan	Sanofi
Holli Hamilton	BARDA
Ian Hirsch	AZ
Laurent Humeau	Inovio
Cheryl Keech	Novavax
Kenneth Koury	Pfizer
Michael Kurilla	NCATS/NIH
Julie Ledgerwood	NIAID/NIH
Maarten Leyssen	J&J
Mary Marovich	NIAID/NIH
Hilary Marston	NIAID/NIH
Stacey Martin	CDC
Jacqueline Miller	Moderna
Kayvon Modjarrad	WRAIR
Kathleen Neuzil	Maryland
Ashley Parker	NIH
Merlin Robb	Henry Jackson Foundation
François Roman	GSK
Jerald Sadoff	J&J
Stephanie Schrag	CDC
Sheri Schully	NIH
Sandra Sitar	VRC/NIH
Saranya Sridhar	Sanofi
Jennifer Verani	CDC
Michael Watson	Moderna

Michael Santos, PhD

COLL0000013800-2517634

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Saturday, October 10, 2020 2:31 PM
To: Santos, Michael (FNIH) [T] <(b) (6)>
Cc: Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>
Subject: Re: Roster of ACTIV Vaccines WG

Can you do me a favor and just pull out the names and institutions of the people who are not on the Vaccines WG?

Sent from my iPhone

On Oct 10, 2020, at 2:21 PM, Santos, Michael (FNIH) [T] <(b) (6)> wrote:

Hi Francis,

We don't maintain as nice of a version of the Sub-Group rosters, but here is the Clinical Trials Sub-Group list of names and organizations (some of which overlap with the main WG). We also commonly have additional guests depending on the topic, so if there's an organization or expertise that you're looking for that is not represented, we can invite them to a meeting ad hoc.

Thanks,
Mike

Name	Organization
Paula Annunziato (co-chair)	Merck
Larry Corey (co-chair)	Fred Hutch
Ann Arvin	Stanford
Beth Bell	UW
Marco Cavaleri	EMA
Myron Cohen	UNC
Elizabeth Desrosiers	Merck
Macaya Douoguih	J&J
Peter Dull	Gates
Emilio Emini	Gates
Emily Erbeling	NIAID/NIH
Gregory M. Glenn	Novavax
Peter Gilbert	SCHARP/UW
Paul Gillard	GSK
Bill Gruber	Pfizer
Marion Gruber	CBER/FDA
Sanjay Gurunathan	Sanofi
Holli Hamilton	BARDA
Ian Hirsch	AZ
Peter Hotez	Baylor and Texas Children's
Laurent Humeau	Inovio

Kathrin Jansen	Pfizer
Cheryl Keech	Novavax
Kenneth Koury	Pfizer
Michael Kurilla	NCATS/NIH
Julie Ledgerwood	NIAID/NIH
Maarten Leyssen	J&J
Doug Lowy	NCI/NIH
Peter Marks	CBER/FDA
Mary Marovich	NIAID/NIH
Hilary Marston	NIAID/NIH
Stacey Martin	CDC
John Mascola	VRC/NIH
Nelson Michael	WRAIR
Jacqueline Miller	Moderna
Kayvon Modjarrad	WRAIR
Kathleen Neuzil	Maryland
Paul Offit	Penn/CHOP
Ashley Parker	NIH
Merlin Robb	Henry Jackson Foundation
François Roman	GSK
Jerald Sadoff	J&J
Stephanie Schrag	CDC
Sheri Schully	NIH
Sandra Sitar	VRC/NIH
Saranya Sridhar	Sanofi
Jennifer Verani	CDC
Michael Watson	Moderna
Tal Zaks	Moderna

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Collins, Francis (NIH/OD) [E] (b) (6)

Sent: Saturday, October 10, 2020 12:47 PM

To: Santos, Michael (FNIH) [T] (b) (6)

Cc: Lane, Cliff (NIH/NIAID) [E] < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) >

Freire, Maria (FNIH) [T] (b) (6) >

Subject: RE: Roster of ACTIV Vaccines WG

Thanks, this is helpful. Have you got a roster of the Clinical Trials Sub-Group?

From: Santos, Michael (FNIH) [T] (b) (6)

Sent: Saturday, October 10, 2020 11:47 AM

To: Collins, Francis (NIH/OD) [E] (b) (6) >

Cc: Lane, Cliff (NIH/NIAID) [E] < (b) (6) > Wholley, David (FNIH) [T] (b) (6)

Freire, Maria (FNIH) [T] < (b) (6) >

Subject: RE: Roster of ACTIV Vaccines WG

COLL0000013800-2517634

Hi Francis,

Sure, I'd be happy to convene a meeting of the WG.

The WG membership is attached. We also have a wider group of people that have been part of the sub-groups, so depending on the topic and the ask we could invite them as well (e.g., for a clinical trials question we could convene the WG plus the Clinical Trials Sub-Group).

For next steps, if we can know a little more about the topic and the desired timing, I'm happy to connect with Kathrin and Doug and schedule a meeting with the appropriate set of people.

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science Foundation for the National Institutes of Health

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Saturday, October 10, 2020 11:33 AM
To: Santos, Michael (FNIH) [T] < > (b) (6)
Cc: Lane, Cliff (NIH/NIAID) [E] (b) (6); Wholley, David (FNIH) [T] (b) (6);
Freire, Maria (FNIH) [T] < > (b) (6)
Subject: Roster of ACTIV Vaccines WG

Hi Mike,

We might need to reconvene the ACTIV Vaccines WG for some advice about management of next steps for the trials. Can you send me the roster?

Francis

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 10/22/2020 3:43:43 PM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fid]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesdener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn | (b) (6) Garner, Carl | (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner | (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Philips, L Revell CIV DTRA RD (USA) | (b) (6) Petrovick, Martha - 0449 - MITLL | (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Derek Smith | (b) (6) Gonzalez, N na [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy (b) (6) Jansen, Kathrin | (b) (6) ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla | (b) (6) ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Dana Carluccio | (b) (6) Rose Li Central Account | (b) (6) ; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderson]. Lucas Smal don | (b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, H.lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) | (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bafd32930-walkerp1]; Bethany Stokes | (b) (6) ; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

Subject: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: ACTIV TX-Clinical Working Group Meeting Guide 20201022.pdf

Location: <https://fnih.zoom.us> (b) (6)

Start: 10/22/2020 5:00:00 PM

End: 10/22/2020 6:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Namish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylvia (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6); Brown, Jeremy (NIH/NINDS) [E]; Gadbors, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6); Sizemore, Christine (NIH/FIC) [E]

Optional Attendees: Derek Smith; Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Saathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Margaret Anderson; Lucas Smalldon; Stratton, Benjamin; (b) (6); Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Ailan (NIH/NHLBI) [E]; Kindzelski, Andre (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today.

Thanks,
Stacey

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]

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| (b) (6) Kim, Elizabeth | (b) (6) btolman [/o=ExchangeLabs/ou=Exchange
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| (b) (6) Prabhavathi Fernandes | (b) (6) Diamond, Michael
| (b) (6)]; Rose Li | (b) (6) Dana Carluccio
| (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
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Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
| (b) (6) Dave Frankowski | (b) (6) Baric, Toni C
| (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188];
Hawk, Harrison | (b) (6) Mason, Stephen | (b) (6)

Subject: ACTIV Preclinical full working group

Attachments: 2020-08-19_Precinical_WG_Summary_F1.docx

Dear WG members and attendees,

Please find the minutes from last week's meeting attached. (sorry for the delay). Please contact me with any modifications or questions.

Looking forward to talking to you in the morning.

Best regards,
Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6) fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-ME_ENCIOC]
Sent: 8/18/2020 3:11:20 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane
| (b) (6) Carter, Kara | (b) (6) Cavaleri, Marco
| (b) (6) Cihlar, Tomas | (b) (6) Collins, Francis (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry
| (b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary
(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Do sten, Mikael
| (b) (6) Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeling]; Erck, Stan
| (b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas
| (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert
(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn
| (b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John
| (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David
| (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy
(CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NARS]; Pandya, Hitesh
| (b) (6) Pangalos, Mene | (b) (6) Pao, William
| (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Paul, Steve
| (b) (6) Perlmutter, Roger | (b) (6) Plenge, Robert | (b) (6)
Plump, Andy | (b) (6)]; Rachel Ramon | [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido
| (b) (6) Reed, John | (b) (6) Reese, David | (b) (6) Rouse, Doris
| (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel
| (b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul
| (b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Tal ey Michael
| (b) (6) Tsai, John | (b) (6) Vessey, Rupert | (b) (6) Virgin,
Skip | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Woodcock, Janet
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John
| (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy

[(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin
 [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa
 [(b) (6) Anderson, Margaret [(b) (6) Chen, Helen
 [(b) (6) Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Tolman, Brett [(b) (6) Tountas Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
 [(b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burkiow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burkiowj]; Castillejos, Carlos [(b) (6)]; FNIH Central Account [(b) (6)]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolnetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolnetzcd]
 CC: Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Bell, Julie [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfield, Anita [(b) (6) Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Krack, Kimberly [kimberly]; [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Lever, Susan [(b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth [(b) (6) Perala, Mie [(b) (6)]; Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Riffin, Mary [(b) (6) Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d97bb3e468057-esuhana]; Thomas, Ashley
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togash, Mieko (NIH/NCI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togash m]; Underwood, Nancy
[(b) (6) Zottoli, Jessica] (b) (6)

Subject: ACTIV Leadership Call #9

Location: <https://fnih.zoom>. (b) (6)

Start: 10/21/2020 4:00:00 PM

End: 10/21/2020 5:00:00 PM

Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauc, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Ras, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, He en; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Peralta, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Marks, Peter | (b) (6) |
Sent: 5/14/2020 1:04:52 PM
To: Mascola, John (N H/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: ChAdOx1

Dear John,

Thanks for bringing the Pfizer issue up. I think that a call with their head of development and possibly also their CEO may be needed, and I wonder if Francis would like to join?

Best Regards,
Peter

From: Mascola, John (NIH/VRC) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 9:03 AM
To: Marks, Peter <(b) (6)> Collins, Francis S (NIH) <(b) (6)> Lane, Henry C (NIH) <(b) (6)>
Cc: Fauci, Anthony S (NIH) <(b) (6)> Wholley, David N (NIH) <(b) (6)> Tabak, Lawrence A (NIH) <(b) (6)> Parker, Ashley S (NIH) <(b) (6)>
Subject: RE: ChAdOx1

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issue is that the Pfizer representative on the subgroup, both Kathrin Jansen (who is co-chair of Vaccines WG), and Bill Gruber (Pfizer Senior VP for R&D) – took turns articulating their view that large Pharma companies like theirs prefer not to work with USG and it would just slow them down. When we asked for suggestions for DSMB, Kathrin said she did not agree that we should ask for nominations – because this issue required more discussion – mainly because Pfizer has no interest in this. Doug Lowy was on the call, so may be useful to get his perspective.

John

From: Marks, Peter (b) (6)
Sent: Thursday, May 14, 2020 6:23 AM
To: Collins, Francis (NIH/OD) [E] (b) (6) Mascola, John (NIH/VRC) [E] (b) (6) Lane,

Cliff (NIH/NIAID) [E] (b) (6)
Cc: Fauci, Anthony (NIH/NIAID) [E] (b) (6) ; Wholley, David (FNIH) [T] (b) (6) ; Tabak,
Lawrence (NIH/OD) [E] (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6)
Subject: RE: ChAdOx1

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Happy to discuss

further.

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 5:38 AM
To: Mascola, John R (NIH) (b) (6) Lane, Henry C (NIH) <(b) (6)> Marks, Peter
(b) (6)
Cc: Fauci, Anthony S (NIH) (b) (6) >; Wholley, David N (NIH) <(b) (6)> ; Tabak, Lawrence A
(NIH) <(b) (6)> , Parker, Ashley S (NIH) <(b) (6)>
Subject: ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 6/12/2020 1:49:37 PM
To: Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [(b) (6) Anderson, Annaliesa [(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Carter, Kara [(b) (6)]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Chiar, Tomas [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [(b) (6) Duncan, Ken [(b) (6) Fernandes, Prabhavathi [(b) (6) Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gatto, Greg [(b) (6) Grobler, Jay [(b) (6) Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [(b) (6) Menetski Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiJP]; Nestle, Frank [(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payne, David [(b) (6) Pitt, Louise [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [(b) (6)]; Rappaport, Jay [(b) (6) Stegmeier, Frank [(b) (6) Young, John [(b) (6)
Subject: FW: Agenda and materials for the Protective Immune Responses Sub-Group meeting
Attachments: Assay WG Tracker _ Updated 6-4.xlsx

Dear Working group,

Our friends in the vaccines group have generated a list that will be interesting to think about.

From below, we should have Janet and Ashley talk to the group about including this list in our online resources?

"Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them."

Joe

From: Santos, Michael (FNIH) [T] <(b) (6)>
Sent: Wednesday, June 10, 2020 9:45 AM
To: Menetski, Joseph (FNIH) [T] <(b) (6)> Alvarez, Rosa Maria <(b) (6)>
Cc: Tolman, Brett <(b) (6)>
Subject: FW: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Hi Joe and Rosa,

I meant to follow up to you last night: FYI on the attached assay tracker from the USG assay WG co chairs (Janet Lathey and Ashley Smith). If there's anything of interest here, Janet Lathey will be at next week's sub-group meeting on this topic.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, June 9, 2020 11:00 PM
To: (b) (6)
Gruber, Marion (FDA/CBER) (b) (6) Marks, Peter (FDA/CBER) <(b) (6)>
(b) (6) Arvin, Ann <(b) (6)> Michael, Nelson L CIV USARMY
MEDCOM WRAIR (USA) (b) (6) Bett, Andrew J (b) (6) Gilbert PhD,
Peter B (b) (6) Kathleen Neuzil <(b) (6)> : Modjarrad, Kayvon CIV USARMY
MEDCOM WRAIR (USA) (b) (6) >; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)
<(b) (6)> : Greg Glenn (b) (6) ; Cavaleri Marco <(b) (6)> Kelly, Beth
<(b) (6)>
Cc: Tolman, Brett (b) (6) ;
(b) (6) ; Jeneffer Haynes (b) (6) Menetski, Joseph (FNIH) [T]
<(b) (6)> : Alvarez, Rosa Maria (b) (6) ; Wholley, David (FNIH) [T] (b) (6)
Parker, Ashley (NIH/OD) [E] (b) (6) ; Brian Rosen (b) (6) >; Cheryl Keech
(b) (6)

Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting at 2:30pm ET (11.30am PT / 6.30pm CEST).

Last week we were fortunate to have Marco Cavaleri present and lead a discussion on EMA regulatory pathways. Development of a table of those pathways analogous to the table developed for FDA pathways is underway.

At this meeting we will return to the topics from two weeks ago: (1) reaching out to collect information on potential signals of human immun.ty and (2) inter-comparability of immunogenicity assays and centralized labs.

Since that meeting Ann and Mark Davis discussed the first topic, and reached out to Dan Rotrosen (Director of the Division of Allergy, Immunology, and Transplantation at NIAID). He is unfortunately unable to join this meeting, but we will discuss the categories of information we would like to collect and the potential process for doing so.

On the second topic, we reached out to Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Wednesday, June 3, 2020 11:30 PM

Subject: Notes from yesterday's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting, and particular thanks to Marco for the excellent presentation and discussion.

Meeting notes are attached, with the meeting materials are embedded. The key action item is develop ng a table of EMA pathways analogous to the one that we previously developed with Marion's input and review for FDA pathways.

Please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Monday, June 1, 2020 1:04 PM

Subject: Agenda and materials for the Protective Immune Responses Sub Group meeting tomorrow (Tuesday)

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting tomorrow (Tuesday) at 8am ET (5am PT / 2pm CEST). We are very sorry for the extremely early start PT.

The main agenda item is to discuss EMA and member state regulatory pathways to vaccine use and approval. Marco will lead the discussion. He previously shared a set of presentation slides (re-attached here). We are also re-attaching the table on FDA pathways that we circulated previously.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Thursday, May 28, 2020 12:57 PM
Subject: Notes and next steps from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting. Notes are attached.

There were two key areas for next steps that we identified in the meeting:

- Potential signals of human immunity:
 - Develop specifics of what we are looking for from immunology research
 - Ask the WG and other contacts for suggestions of researchers/organizations worth reaching out to
 - Reach out and collect information and contacts to engage with the WG (in presentations or other formats)
- Inter-comparability of immunogenicity assays / centralized labs
 - Reach out to NIAID to learn more about planned centralized lab capabilities and timing

Ann kindly followed up with an initial set of recommendations for the first area. We'll be following up to develop the list of information that we'd like to gather and to discuss how to prioritize whom we reach out to. We'll reach out to NIAID and report back on the second area.

We think these topics will form the basis for future discussions, but we are also trying to schedule a meeting for a time when we can have a discussion about the EMA regulatory pathways with Marco, to complement the conversations we have had on FDA pathways. We hope to have an invite for that out soon.

As always, please reach out with any additional input on the notes, questions, or suggestions for future directions for this group.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 11:42 PM
Subject: Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For

today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 12:19 AM
Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 19, 2020 8:56 AM
Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

(b) (6) | fnih.org

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From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/16/2020 6:15:43 PM
To: Jessica (NIH/OD) Tucker [E] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbef0fb5e52c31a4-tuckerjm]
Subject: FYI: ACTIV slides from today on escape mutations
Attachments: 12.16 ACTIV EC and Leadership Team Meeting 20201215 vF (003).pdf; 12.16 ACTIV EC and Leadership Team Meeting_APPENDIX 20201215 vF.pdf; 2020-11-19 ACTIV Leadership Team Meeting_Summary v3.pdf

See slides 6-10. Note that slide 8 includes "selection screens." There was general enthusiasm on the call today for the general effort and FC asked industry members what they could do to help. Skip Virgin from VIR said that there are certain experiments that FDA is also asking sponsors to conduct and so centralizing assays and information was important. There was then discussion of a platform that FDA/BARDA/OWS has apparently already built that takes sequence data, makes pseudotype viruses, and run them against a panel of antibodies. (I had to look up pseudotyping—it sounds like it is making a replication incompetent virus.) Not much more detail.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 6:29 PM
To: Wholley, David (FNIH) [T] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)>
Bancel, Stephane <(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]
<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
Victoria Davey <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael
<(b) (6)> Erbeling, Emily (NIH/NIAID) [E] <(b) (6)> Erck, Stan
<(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Freire, Maria (FNIH) [T]
<(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E]
<(b) (6)> Hudson, Thomas <(b) (6)> James, Stephanie (FNIH) [T]
<(b) (6)> Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> Kramer, Lynn
<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Lepore, John <(b) (6)>
Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary (NIH/NIAID) [E] <(b) (6)>
Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David <(b) (6)> Menetski, Joseph
(FNIH) [T] <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh
<(b) (6)> Pangalos, Mene <(b) (6)> Pao, William
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Paul, Steve <(b) (6)>
Perlmutter, Roger <(b) (6)> Plenge, Robert <(b) (6)> Plump, Andy
<(b) (6)> Rachel Ramoni <(b) (6)> Reed, John <(b) (6)> Reese,
David <(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)>
Skovronsky, Daniel <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul
<(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Talley, Michael
<(b) (6)> Tsai, John <(b) (6)> Vessey, Rupert <(b) (6)> Virgin, Skip
<(b) (6)> Woodcock, Janet (FDA/CDER) <(b) (6)> Young, John
<(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy
<(b) (6)> Eric Hughes <(b) (6)> Jansen, Kathrin
<(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI)
<(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)>
Adam, Stacey (FNIH) [T] <(b) (6)> Margaret Anderson <(b) (6)> Appell, Evan
<(b) (6)> Chen, Helen Q. <(b) (6)> Connelly, Sarah <(b) (6)>
Gonzalez, Nina <(b) (6)> Hawk, Harrison <(b) (6)> Mendelson, Jesse
<(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Nasr, Hana <(b) (6)>
Santos, Michael (FNIH) [T] <(b) (6)> Sorosa, Alex David <(b) (6)> Stratton, Benjamin
<(b) (6)> btolman <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)>
Wachtel, Jonathan <(b) (6)>

Cc: Anderson, James (NIH/OD) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E]
<(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)> Carluccio, Dana
<(b) (6)> Castillejos, Carlos <(b) (6)> FNIH Central Account
<(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)> : Lane, Cliff (NIH/NIAID) [E]
<(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E]
<(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E]
<(b) (6)> Meltzer, Abbey (FNIH) [T] <(b) (6)>

Subject: RE: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION

Dear ACTIV Leadership Team and meeting attendees:

Please see corrected version of materials. Sorry for the confusion.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> > On Behalf Of Wholley, David (FNIH) [T]

Sent: Tuesday, December 15, 2020 5:08 PM

To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane

<(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
<(b) (6)> >; Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]

<(b) (6)> >; Corey, Larry <(b) (6)> ; Culp, Michelle (NIH/OD) [E] <(b) (6)>

Victoria Davey <(b) (6)> . Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> >; Dolsten, Mikael

<(b) (6)> Erbeling, Emily (NIH/NIAID) [E] <(b) (6)> ; Erck, Stan

<(b) (6)> . Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> . Freire, Maria (FNIH) [T]

<(b) (6)> , Gadbois, Ellen (NIH/OD) [E] <(b) (6)> , Gibbons, Gary (NIH/NHLBI) [E]

(<(b) (6)> Hudson, Thomas <(b) (6)> James, Stephanie (FNIH) [T]

<(b) (6)> ; Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> Kramer, Lynn

<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> ; Lepore, John <(b) (6)>

Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary (NIH/NIAID) [E] <(b) (6)>

Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David <(b) (6)> Menetski, Joseph

(FNIH) [T] <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh

<(b) (6)> ; Pangalos, Mene <(b) (6)> >; Pao, William

<(b) (6)> ; Parker, Ashley (NIH/OD) [E] <(b) (6)> Paul, Steve <(b) (6)>

Perlmutter, Roger <(b) (6)> >; Plenge, Robert <(b) (6)> >; Plump, Andy

<(b) (6)> Rachel Ramoni <(b) (6)> >; Reed, John <(b) (6)> >; Reese,

David <(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)>

Skovronsky, Daniel <(b) (6)> >; Stein, Peter (FDA/CDER) <(b) (6)> >; Stoffels, Paul

<(b) (6)> ; Tabak, Lawrence (NIH/OD) [E] <(b) (6)> ; Talley, Michael

(b) (6) >; Tsai, John < (b) (6) Vessey, Rupert (b) (6) >; Virgin, Skip
 (b) (6) ; Wholley, David (FNIH) [T] (b) (6) ; Woodcock, Janet (FDA/CDER)
 < (b) (6) Young, John (b) (6) >; Colvis, Christine (NIH/NCATS) [E]
 (b) (6) ; Desrosiers, Betsy (b) (6) ; Eric Hughes
 (b) (6) ; Jansen, Kathrin (b) (6) ; Kurilla, Michael (NIH/NCATS) [E]
 (b) (6) ; Lowry, Douglas (NCI) (b) (6) ; Read, Sarah (NIH/NIAID) [E] (b) (6)
 Young, John (b) (6) Adam, Stacey (FNIH) [T] (b) (6) Margaret Anderson
 < (b) (6) Appell, Evan (b) (6) ; Chen, Helen Q. (b) (6) ;
 Connelly, Sarah (b) (6) , Gonzalez, Nina < (b) (6) Hawk, Harrison
 (b) (6) ; Mendelson, Jesse (b) (6) >; Menetski, Joseph (FNIH) [T]
 (b) (6) >; Nasr, Hana (b) (6) >; Santos, Michael (FNIH) [T] (b) (6) >; Sorosa,
 Alex David (b) (6) >; Stratton, Benjamin (b) (6) ; btolman < (b) (6)
 Tountas, Karen (FNIH) [T] < (b) (6) ; Wachtel, Jonathan (b) (6) ; Wholley, David (FNIH) [T]
 (b) (6)
Cc: Anderson, James (NIH/OD) [E] < (b) (6) Austin, Christopher (NIH/NCATS) [E]
 (b) (6) Burklow, John (NIH/OD) [E] < (b) (6) >; Carluccio, Dana
 < (b) (6) Castillejos, Carlos (b) (6) >, FNIH Central Account
 < (b) (6) Hallett, Adrienne (NIH/OD) [E] (b) (6) Lane, Cliff (NIH/NIAID) [E]
 (b) (6) ; My.es, Renate (NIH/OD) [E] (b) (6) ; Parker, Ashley (NIH/OD) [E]
 < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Wolinetz, Carrie (NIH/OD) [E]
 (b) (6) ; Meltzer, Abbey (FNIH) [T] < (b) (6)

Subject: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, December 16, 10:00 – 11:30 a.m. Eastern U.S. Time.** The minutes from the November 19 Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

Join Zoom Meeting

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Dial by your location

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 (b) (6) US (Chicago)
 (b) (6) US (New York)
 (b) (6) US (San Jose)
 (b) (6) US (San Jose)
 (b) (6) US (Tacoma)
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 (b) (6) Belgium
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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
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CC: Chen, Helen Q. [(b) (6)]; Wachtel, Jonathan [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A. [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Kenny, Dermot [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Pett, Sarah [(b) (6)]; Grace, Beth (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Barrett, Kevin (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrett2]; Denning, Eileen [(b) (6)]; Baseler, Beth (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2363525c118a468b9e8f5f61707c63f5-bbaseler]; Engel, Theresa (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e86305ea82754e65b67a63591ed867ba-engelt]
Subject: Follow-up from ACTIV-3 Operations Team Meeting 06/16/2020
Attachments: ACTIV Therapeutics-Clinical Master Protocol Subgroup ACTIV-3 Operations Team Meeting_20200616.pdf; ACTIV-3operations16June2020.pdf; ACTIV3_INSIGHT014_16June2020.pdf

Dear ACTIV-3 Operations Team,

Please find attached the quick capture high level summary points and action items from today's meeting. In addition, I have attached the slides from both Jim and Jens' presentations.

Please let us know if you have any questions or amendments.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
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 Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: Follow-up from ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Attachments: 2020-05-03 TX-Clinical WG Agent Prioritization Subgroup_Summary.pdf

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Thank you all once again for a very productive meeting yesterday, and especially thank for the extra hour and a half that you gave to the discussion. I appreciate that you helped us get to a good set of selections for our first round and that you helped us learn a lot about how to refine the process.

Please find attached the official summary of yesterday's call. Please let me know if you feel and additions or amendments are needed to accurately reflect the record of our discussions. Please keep in mind that this will be the official record of our first meeting, so review with that eye for any necessary details.

We will send the materials out for tomorrow's call tomorrow AM, but the main focus of our call will be to debrief on our final review meeting and suggestions for improving the next round.

Thanks,
Stacey

Stacey J. Adam, PhD

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Director, Cancer
Research Partnerships

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Subject: Fwd: Materials for Tomorrow, Wednesday, November 4 ACTIV Executive Committee Teleconference
Attachments: 11.4 ACTIV Executive Committee Meeting 20201103 FINAL.pdf; ATT00001.htm; 11.4 ACTIV Executive Committee Meeting 20201103 Appendix (002).pdf; ATT00002.htm; 2020-10-21 ACTIV Leadership Team Meeting Summary-FINAL.docx; ATT00003.htm; 2020-10-07_Executive_Committee_Meeting_Summary_FINAL.docx; ATT00004.htm

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Ashley Parker, Ph.D.

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From: "Wholley, David (FNIH) [T]" <(b) (6)>
To: "Collins, Francis (NIH/OD) [E]" <(b) (6)> "Disbrow, Gary (OS/ASPR/BARDA)" <(b) (6)> "Dolsten, Mikael" <(b) (6)> "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)> "Gibbons, Gary (NIH/NHLBI) [E]" <(b) (6)> "Marks, Peter (FDA/CBER)" <(b) (6)> "Pao, William" <(b) (6)> "Plump, Andrew" <(b) (6)> "Stoffels, Paul" <(b) (6)> "Woodcock, Janet (FDA/CDER)" <(b) (6)> "Colvis, Christine (NIH/NCATS) [E]" <(b) (6)> "Desrosiers, Betsy" <(b) (6)> "Eric Hughes" <(b) (6)> "Jansen, Kathrin" <(b) (6)> "Kurilla, Michael (NIH/NCATS) [E]" <(b) (6)> "Lowy, Douglas (NCI)" <(b) (6)> "Read, Sarah (NIH/NIAID) [E]" <(b) (6)> "Young, John" <(b) (6)> "Adam, Stacey (FNIH) [T]" <(b) (6)> "Margaret Anderson" <(b) (6)> "Appell, Evan" <(b) (6)> "Chen, Helen Q." <(b) (6)> "Connelly, Sarah" <(b) (6)> "Gonzalez, Nina" <(b) (6)> "Hawk, Harrison" <(b) (6)> "Mendelson, Jesse" <(b) (6)> "Menetski, Joseph (FNIH) [T]" <(b) (6)> "Santos, Michael (FNIH) [T]" <(b) (6)> "asorosa" <(b) (6)> "Stratton, Benjamin" <(b) (6)> "btolman" <(b) (6)> "Tountas, Karen (FNIH) [T]" <(b) (6)> "Wachtel, Jonathan" <(b) (6)> "Wholley, David (FNIH) [T]" <(b) (6)> "Anderson, James (NIH/OD) [E]" <(b) (6)> "Austin, Christopher (NIH/NCATS) [E]" <(b) (6)> "Burklow, John (NIH/OD) [E]" <(b) (6)> "Carluccio, Dana" <(b) (6)> "Castillejos, Carlos" <(b) (6)> "Culp, Michelle (NIH/OD) [E]" <(b) (6)> "FNIH Central Account" <(b) (6)> "Freire, Maria (FNIH) [T]" <(b) (6)> "Gadbois, Ellen (NIH/OD) [E]" <(b) (6)> "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)> "Myles, Renate (NIH/OD) [E]" <(b) (6)> "Parker, Ashley (NIH/OD) [E]" <(b) (6)> "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)> "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)> "Gorman, Greta (FNIH) [T]" <(b) (6)> "Meltzer, Abbey (FNIH) [T]" <(b) (6)>
Cc: "Barasch, Kimberly (NIH/NIAID) [C]" <(b) (6)> "Barasch, Kimberly (NIH/NIAID) [C]" <(b) (6)> "Conrad, Patricia (NIH/NIAID) [E]" <(b) (6)> "Dimishkov, Roxanne (NIH/NHLBI) [C]" <(b) (6)> "McManus, Ayanna (NIH/OD) [E]" <(b) (6)> "Perala, Mie" <(b) (6)> "Protasiewicz, Ann" <(b) (6)>

(b) (6) , "Riccobene, Kim" (b) (6) "Thomas, Ashley
(FDA/CDER)" (b) (6) , "Wood, Gretchen (NIH/OD) [E]" (b) (6) ,
"Togashi, Mioko (NIH/NCI) [E]" < (b) (6) , "Underwood, Nancy"
(b) (6) , "Zottoli, Jessica" < (b) (6) , "Burrus-Shaw, Cyndi
(NIH/OD) [E]" < (b) (6) , "Carver, Trea (NIH) [C]" < (b) (6) , "Hughes,
Karen (NIH/OD) [E]" (b) (6) > , "Lagos, Enrique (NIH/NCATS) [E]"
(b) (6) > , "Melencio, Cheryl (FNIH) [T]" < (b) (6) , "Sepulveda, Dorina
(FNIH) [T]" (b) (6) , "Simon, Dina (NIH/OD) [C]" (b) (6) > , "Tajalli, Ada
(NIH/OD) [E]" (b) (6)

**Subject: Materials for Tomorrow, Wednesday, November 4 ACTIV Executive Committee
Teleconference**

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from **10:00 a.m. – 11:00 a.m. U.S. Eastern time, tomorrow, Wednesday, November 4**. I have also attached notes from our October 21 Leadership Team meeting as well as our last EC meeting on October 7.

The Zoom Information is:

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Please let Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Cohen, Myron
 [(b) (6)]; Victoria Davey [(b) (6) Desrosiers, Betsy
 [(b) (6)]; Dickens, Jim (NIH/NCATS) [C] (b) (6)]; Doroshov, James
 (NIH/NCI) [E] [(b) (6) Goff, David (NIH/NHLBI) [E] [(b) (6) Kurilla, Michael
 (NIH/NCATS) [E] [(b) (6) Nayak, Seema (NIH/NIAID) [E] [(b) (6) Payton, Manizhe
 (NIH/NIAID) [E] [(b) (6) Resnansky, Laura [(b) (6) Srinivasan, Badhri
 [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Weinmann, Gail (NIH/NHLBI)
 [E] [(b) (6)]; Kublin MD, MPH, James (b) (6) Ferguson, Sue
 [(b) (6) Mensah, George (NIH/NHLBI) [E] [(b) (6)]; Vincent, Mike
 [(b) (6) Bascles, Lionel [(b) (6) Corey, Larry [(b) (6)
 Garner, Carlos [(b) (6) Sizemore, Christine (NIH/FIC) [E] [(b) (6)
CC: Wachtel, Jonathan (b) (6)]; Colvis, Christine (NIH/NCATS) [E] [(b) (6) Jansen,
 Kathrin [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E]
 [(b) (6)]; Young, John (b) (6) Adam, Stacey (FNIH) [T] [(b) (6)
 Anderson, Margaret [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];
 Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Gonzalez,
 Nina [(b) (6) Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T]
 [(b) (6) Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6)
 Qashu, Felicia (NIH/OD) [E] [(b) (6)]; Santos, Michael (FNIH) [T] [(b) (6) Tuveson, Nancy
 [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Criffie, Robin
 [(b) (6) Hamilton, Nancy [(b) (6) Hill, Zoe (NIH/NHLBI) [C]
 [(b) (6) Minnich, Beth [(b) (6) Mueller-Reichenstein, Petra [petra.mueller-
 reichenstein@novartis.com]; Pico, Dianna (NIH/NHLBI) [C] [(b) (6) Quadros, Nora
 [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [(b) (6) Culp, Michelle (NIH/OD) [E]
 [(b) (6) Kenny, Dermot [(b) (6) (b) (6) Gadbois,
 Ellen (NIH/OD) [E] [(b) (6) Chen, Jue (NIH/NHLBI) [E] (b) (6)
 [(b) (6) (b) (6) (b) (6)
 [(b) (6) Iturriaga, Erin (NIH/NHLBI) [E] [(b) (6) Rosenberg, Yves (NIH/NHLBI)
 [E] [(b) (6) Lash, Tiffani (NIH/NIBIB) [E] [(b) (6) Merchak, Todd (NIH/NIBIB) [E]
 [(b) (6)]; Pearson, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb1e26f1e264499aa898a482fe0b4045-pearsong], Hughes, Eric
 [(b) (6)]

Attachments: Clinical Trial Capacity Working Group Meeting Agenda 06022020 pdf

Location: <https://fnih.zoom.us/j/> (b) (6)

Start: 6/2/2020 1:00:00 PM

End: 6/2/2020 2:00:00 PM

Recurrence: (none)

Required Attendees: Mensah, George; Vincent, Mike; Bascles, Lionel; Corey, Larry; Garner, Carlos; Cohen, Myron; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Michael; Nayak, Seema (NIH/NIAID) [E]; Payton, Manizhe; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Weinmann, Gail; Kublin MD, MPH, James; Ferguson, Sue

Optional Attendees: Gadbois, Ellen (NIH/OD) [E]; Chen, Jue (NIH/NHLBI) [E]; (b) (6)
 (b) (6) (b) (6) (b) (6) Iturriaga, Erin (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Pearson, Gail (NIH/NHLBI) [E]; Lash, Tiffani (NIH/NIBIB) [E]; Merchak, Todd (NIH/NIBIB) [E]; Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] [(b) (6) Carluccio, Dana; Cheryl (FNIH) Melencio [T] [(b) (6) Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffie, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI)

[C]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E]
(b) (6) Culp, Michelle (NIH/OD) [E]; Kenny, Dermot; (b) (6)

Dear Colleagues, Attached is the meeting agenda, we'll be welcoming the RADx team to this meeting and hearing about their activities. Best regards, Karen

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate looking forward to operationalizing the outcomes of your efforts. Let's continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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From: Tountas Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 6/8/2020 6:32:49 PM
To: Bascles, Lionel [(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron-cohen]; Corey, Larry [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshov]; Garner, Carlos [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294c/bb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Takas, Therese [(b) (6) Vincent, Mike [(b) (6) Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Kenny, Dermot [(b) (6) Wachtel, Jonathan [(b) (6)
Subject: CT Capacity WG agenda and survey Dashboard review
Attachments: Clinical Trial Capacity Working Group Meeting Agenda 06092020.pdf

Dear Clinical Trial Capacity Working Group,

Attached is the agenda for the full WG call tomorrow

Please note that there will be some time to provide feedback regarding the Network/Site/CRO/SMO dashboard. I encourage all of you to take a few moments to review the dashboard ahead of the call tomorrow. Please think about additional features that will make this more user friendly and more useful. The Deloitte dashboard team is very responsive to requests that can be accommodated by the Tableau platform.

Dashboard link: https://analyticsqa.ama.nih.gov/#site/ACTIVE/views/ACTIVE/CTCapacityWGSurveyDashboard/Network-SiteMap?_id=1

Many thanks!
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
(b) (6) fnih.org

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CC: Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh], Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Jhoanna Roa [(b) (6) Eron, Joseph J Jr (b) (6) Smith, David [(b) (6) Paul Klekotka [(b) (6) Ajay Nirula [(b) (6) Chen, Helen Q. [(b) (6)
Subject: Joint ACTIV-2 and ACTIV-3 Writing Team Meeting
Location: <https://fnih.zoom.us> (b) (6)
Start: 6/4/2020 4:00:00 PM
End: 6/4/2020 5:00:00 PM
Show Time As: Tentative

Required Attendees: Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Manna (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Judy Currier; Karen Lynn Price; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; Price, Dionne (FDA/CDER); Rubin, Danie B. (FDA/CDER); Farley, John (FDA/CDER); (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) ; (b) (6) (b) (6) Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6) Kim, Peter (NIH/NIAID) [E]
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan, El zabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.

Stacey Adam is inviting you to a scheduled Zoom meeting.

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Subject: ACTIV partnership on COVID-19
Attachments: FNIH Covid 19 meeting April 03 2020 notes.docx

Dear Colonel Michael,

I am writing to you at the suggestion of Brigadier General Michael Talley. As you know well, addressing the COVID-19 pandemic is an urgent priority for the entire biomedical research community. While the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond, the field needs to find a way to focus and prioritize these many efforts, as there is a critical need for effective treatments and vaccines.

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and of course working with other government agencies and individual companies on accelerated testing of vaccines and therapeutics. In order to broaden the response on April 17 we announced ACTIV, a new public-private partnership with FDA, BARDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics. We have since added representatives from the Veterans Administration and, in recognition of the valuable work and capabilities of the DoD in these and other fields of medical research, approached BG Talley earlier this week to see if there would be interest in adding representatives from the Department to our partnership.

As described in the attached meeting notes (from our kick-off on April 3) we have now set up Working Groups to decide efforts in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development. At the suggestion of BG Talley, I would like to invite you to join as a member on the Vaccines Working Group which is being co-chaired by Doug Lowy, NCI and Kathrin Jansen, Pfizer. While this group has been meeting for several weeks, there are many decisions still to be made and many areas of discussion that can benefit from your insights and expertise.

Please direct your response to this invitation to Mike Santos (b) (6) of the Foundation for the NIH, who will fill you in on the mission and progress of the Working Group and get you integrated into meeting logistics. Look forward to your contributions to this critical effort.

Best,
Francis Collins

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan | (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US (b) (6)
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #9
Location: <https://fnih.zoom>. (b) (6)
Start: 4/27/2020 6:00:00 PM
End: 4/27/2020 7:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylvia (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael

Optional Attendees: Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/15/2021 6:40:39 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Follow up on plan for a pragmatic clinical trial platform to test public interest drugs

One thing I forgot to mention. There was some talk on one of our calls about the UK considering a trial of this kind. Good subject to bring up with Jeremy Farrar—and perhaps a reason to schedule that call sooner rather than later.

From: Wholley, David (FNIH) [T]
Sent: Friday, January 15, 2021 9:41 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Freire, Maria (FNIH) [T] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E] <(b) (6)> Patterson, Amy (NIH/NHLBI) [E] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: Follow up on plan for a pragmatic clinical trial platform to test public interest drugs

Hi Francis,

As promised, I spoke with Stacey. The plan is:

- 1) Getting additional information. We need answers to three questions:
 - a. The Gates Foundation may have plans and certainly has resources to do a trial like this. The TX Clinical WG agreed it is very important to understand what they are up to and what they could offer in that regard. Jacqueline Kirchner was on the WG call and will work with Stacey to set up a call with the appropriate leadership at Gates to find this out.
 - b. We need to have discussion with the ACTIV 2 team to confirm whether this is something they could take on and if so how, and how fast.
 - c. A similar discussion with ACTIV-4, including their SIREN network folks. Stacey is reaching out on b. and c.
- 2) High level meeting to decide best course of action (existing platform outside of ACTIV vs. modify or extend existing ACTIV trial vs. design and launch an "ACTIV-5" trial). Would include the TX WG co-chairs (Sarah Read and Eric Hughes), the ACTIV2/3 TOC co-chairs (Janet Woodcock and Cliff Lane), and representatives from one or all of the groups referred to above, depending on what comes out of the fact-finding in step 1. Stacey is working to set this up in parallel with step 1 since calendars are likely not easy.
- 3) Follow-on meeting with the Tx Clinical WG to discuss what the high level group recommends and how to get this done, plan to move forward.

By the way,

(b) (5)

Thanks, David

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

(b) fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852



To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]; (b) (6)
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 Ottinger, Elizabeth (NIH/NCATS) [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E]
 [(b) (6)]; Hewitt, Judith (NIH/NIAID) [E] [(b) (6)]; Deming, Damon (FDA/CDER)
 [(b) (6) (b) (6) (b) (6) Parker,
 Ashley (NIH/OD) [E] [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
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 (b) (6) Adams, Peter (OS/ASPR/BARDA) [(b) (6)];
 (b) (6)

CC: Wholley, David (FNIH) [T] [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Colvis, Christine
 (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Hughes, Eric
 [(b) (6)]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
 [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E]
 [(b) (6)]; Tountas, Karen (FNIH) [T] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6)
 James, Stephanie (FNIH) [T] [(b) (6) Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth
 [(b) (6)]; Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6)
 Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio
 [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6) Gonzalez, Nina
 [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E]
 [(b) (6) Rodriguez, Robin D [(b) (6) Dave Frankowski
 [(b) (6) Baric, Toni C [(b) (6) Santos, Michael (FNIH) [T]
 [(b) (6) Austin, Christopher (NIH/NCATS) [E] [(b) (6) Diamond, Michael
 [(b) (6) Jonson, Samantha (NIH/NCATS) [E] [(b) (6)

Start: 4/21/2020 6:00:00 PM

End: 4/21/2020 7:00:00 PM

Recurrence: (none)

Optional Attendees: Wholley, David (FNIH) [T], Austin, Christopher (NIH/NCATS) [E], Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E], Lowy, Douglas (NCI), Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li, Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski, Baric, Toni C

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(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6)]

Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]. (b) (6)

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Fernandes [(b) (6)	Diamond, Michael [(b) (6)	Rose Li
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Gadbois, El en (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group				
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Mason, Stephen [(b) (6)	(b) (6)	(b) (6)	Connelly, Sarah
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(b) (6)	(b) (6)	Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group	(b) (6)	(b) (6)
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd				
[(b) (6)	(b) (6)	(b) (6)	(b) (6)

Subject: Canceled: ACTIV Preclinical full working group

Start: 12/23/2020 3:00:00 PM

End: 12/23/2020 4:00:00 PM

Show Time As: Free

Recurrence: (none)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Tountas Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 6/15/2020 7:48:50 PM
To: Vincent, Mike [(b) (6) Bascles, Lionel [(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myrone-cohen]; Corey, Larry [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria-da]; Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Kublin MD, MPH, James [(b) (6) Ferguson, Sue [(b) (6)
CC: Takas, Therese [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboise]; Hughes, Eric [(b) (6) Wachtel, Jonathan [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathryn [(b) (6)]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, N.na [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6) Hamilton, Nancy [(b) (6) Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Minnich, Beth
[(b) (6) Mueller-Reichenstein, Petra [(b) (6) Pico, Dianna
(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-p codf]; Quadros, Nora
[(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Culp, Michelle (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Kenny, Dermot
[(b) (6) (b) (6)

Subject: Canceled: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Location: <https://fnih.zoom.us>: (b) (6)

Start: 6/16/2020 1:00:00 PM

End: 6/16/2020 2:00:00 PM

Show Time As: Free

Recurrence: Weekly
every Tuesday from 9:00 AM to 10:00 AM

Required Attendees: Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim
(NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurila, Mike; Mensah,
George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzone; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E];
Srinivasan, Badhri; Stein, Peter (FDA/CDER); Weinmann, Gail; Kublin MD, MPH, James; Ferguson, Sue
Optional Attendees: Takas, Therese; Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E];
Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson,
Margaret; Ashley (NIH/OD) Parker [E]; (b) (6) Carluccio, Dana, Cheryl (FNIH) Melencio [T]
(b) (6) Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T];
Qashu, Felicia, Santos, Michael (FNIH); Tuveson, Nancy; Wholey, David (FNIH) [T]; Criffield, Robin, Hamilton, Nancy;
Hill, Zoe (NIH/NHLBI) [C]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca
(NIH/NCATS) Katz [E]; (b) (6) Culp, Michelle (NIH/OD) [E]; Kenny, Dermot;
(b) (6)

Dear Clinical Trial Capacity Working Group Members – This **call will be canceled for 16 June 2020**. You get 1
hour back to your week – Enjoy! The **next call for the working group is scheduled for 23 June 2020** at 9 am
eastern US time. Best regards, Karen

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our
ACTIV mandate – looking forward to operationalizing the outcomes of your efforts. Let's continue to meet
regularly through the month of June (once a week) to continue to build out the inventories of
CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV
working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 10/17/2020 1:15:59 PM
To: Gavin, Brian [(b) (6)]
Subject: RE: 1st ACTIV-1 patient has been randomized

Hey Brian,

Wow, that takes me back to those days in SHM, where Chris Stoeckert, Marsha Newman, and I hung out in the decommissioned P3 lab across the hall from the Ward lab. It's great that paths of your efforts and mine have now crossed again. Go ACTIV-1!

Best, Francis

From: Gavin, Brian < (b) (6) >
Sent: Friday, October 16, 2020 6:13 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Subject: RE: 1st ACTIV-1 patient has been randomized

Hi Francis,

I don't know if you remember me but I was a grad student in Dave Ward's lab at Yale while you were doing work with Sherm Weissman. I was in Human Genetics and a good friend of Jim Metherall. We definitely crossed paths but given your career there are certainly a lot of people that can say that! Anyway, I just thought I would say hello and also tell you what a pleasure it has been to work with the whole NIH/NCATS team.

Best Regards,
Brian Gavin

From: Collins, Francis (NIH/OD) [E] < (b) (6) >
Sent: Friday, October 16, 2020 5:46 PM
To: Bozzette, Sam (NIH/NCATS) [E] < (b) (6) >; Boucher, Cynthia (NIH/NCATS) [E] < (b) (6) >; Atkinson, Jane (NIH/NCATS) [E] < (b) (6) >; Chang, Soju (NIH/NCATS) [E] < (b) (6) >; Sadeh, Jonathan < (b) (6) >; 'Melsheimer, Rich [CNTNL]' < (b) (6) >; 'Beumont-Mauviel, Maria [JRDUS]' < (b) (6) >; 'Bharucha_David' < (b) (6) >; 'Ferguson_William' < (b) (6) >; 'Eric Hughes' < (b) (6) >; Read, Sarah (NIH/NIAID) [E] < (b) (6) >; 'LaVange, Lisa M' < (b) (6) >; Proschan, Michael (NIH/NIAID) [E] < (b) (6) >; 'Sandeep Menon' < (b) (6) >; 'Yong, Florence H' < (b) (6) >; Trank, Christina < (b) (6) >; 'Moyo, Vusi' < (b) (6) >; 'Kimmel, Bridget [JRDUS]' < (b) (6) >; Adam, Stacey (FNIH) [T] < (b) (6) >; Marti, Emily (NIH/NCATS) [E] < (b) (6) >; Eisnor, Derek (OS/ASPR/BARDA) < (b) (6) >; Woodcock, Janet (FDA/CDER) < (b) (6) >; Mason, Robin (OS/ASPR/BARDA) < (b) (6) >; O'Sullivan_Alexandra < (b) (6) >; Stock, Thomas (HHS/IOS) < (b) (6) >; Neta Nelson < (b) (6) >; Butler, Sandy < (b) (6) >; Daniel Benjamin Jr, M.D., Ph.D. < (b) (6) >; Theresa Jasion < (b) (6) >; Molina, Daniel < (b) (6) >; Rose Beci < (b) (6) >; Lind, Brian (NIH/NCATS) [E] < (b) (6) >; Mason, Robin (OS/ASPR/BARDA) < (b) (6) >

(b) (6) O'rourke, Anna (OS/ASPR/BARDA) (CTR) <Anna. (b) (6) Austin, Christopher
(NIH/NCATS) [E] (b) (6) >; Lori Hudson, Ph.D. < (b) (6) "Huyen Cao"
< (b) (6) <"Huyen Cao" < (b) (6) Huyen Cao < (b) (6) Brody, Betty
(OS/ASPR/BARDA) (b) (6) ; Chiang, Anna (OS/ASPR/BARDA) (b) (6) >; Schmidt, Jeffrey
(OS/ASPR/BARDA) (b) (6) >
Subject: RE: 1st ACTIV-1 patient has been randomized

[Use CAUTION when opening links/attachments]

Terrific! I just talked about the study with Wolf Blitzer on CNN – it's great to have it underway.

Many thanks to all who worked so hard to get to this point. Onward!

Francis

From: Bozzette, Sam (NIH/NCATS) [E] (b) (6)
Sent: Friday, October 16, 2020 4:48 PM
To: Boucher, Cynthia (NIH/NCATS) [E] < (b) (6) Atkinson, Jane (NIH/NCATS) [E]
< (b) (6) Chang, Soju (NIH/NCATS) [E] < (b) (6) ' (b) (6)
<wpowder (b) (6) 'Gavin, Brian' < (b) (6) 'Sadeh, Jonathan' < (b) (6)
'Melsheimer, Rich [CNTNL]' (b) (6) 'Beumont-Mauviel, Maria [JRDUS]' (b) (6)
'Bharucha_David' < (b) (6) ; 'Ferguson_William' < (b) (6) >; Eric Hughes
(b) (6) ; Read, Sarah (NIH/NIAID) [E] (b) (6) ; 'LaVange, Lisa M'
< (b) (6) Proschan, Michael (NIH/NIAID) [E] (b) (6) Gardner, Bobbi (NIH/NCATS) [E]
(b) (6) >; 'Sandeep Menon' (b) (6) 'Yong, Florence H'
< (b) (6) ; 'Trank, Christina' (b) (6) ; 'Moyo, Vusi'
(b) (6) Collins, Francis (NIH/OD) [E] (b) (6) 'Kimmel, Bridget [JRDUS
< (b) (6) ; Adam, Stacey (FNIH) [T] (b) (6) Marti, Emily (NIH/NCATS) [E]
< (b) (6) Eisnor, Derek (OS/ASPR/BARDA) (b) (6) >; (b) (6)
< (b) (6) Austin, Christopher (NIH/NCATS) [E] < (b) (6) Collins, Francis (NIH/OD) [E]
< (b) (6) Woodcock, Janet (FDA/CDER) (b) (6) Mason, Robin (OS/ASPR/BARDA)
< (b) (6)
Cc: 'Montgomery, Stephanie' < (b) (6) O'Sullivan_Alexandra
(b) (6) ; Stock, Thomas (HHS/IOS) (b) (6) >; Neta Nelson
(b) (6) >; Butler, Sandy (b) (6) >; Daniel Benjamin Jr, M.D., Ph.D.
< (b) (6) Theresa Jasion < (b) (6) Molina, Daniel < (b) (6)
Rose Beci (b) (6) Lind, Brian (NIH/NCATS) [E] (b) (6) Mason, Robin (OS/ASPR/BARDA)
(b) (6) ; O'rourke, Anna (OS/ASPR/BARDA) (CTR) <Anna. (b) (6) Austin, Christopher
(NIH/NCATS) [E] < (b) (6) Lori Hudson, Ph.D. (b) (6) ; "Huyen Cao"
< (b) (6) <"Huyen Cao" < (b) (6) Huyen Cao < (b) (6) ; Brody, Betty
(OS/ASPR/BARDA) (b) (6) ; Chiang, Anna (OS/ASPR/BARDA) (b) (6) >; Schmidt, Jeffrey
(OS/ASPR/BARDA) < (b) (6)
Subject: 1st ACTIV-1 patient has been randomized

Hello:

The first patient has been randomized into ACTIV-1. Congratulations to all, especially Bill Powderly, Jane O'Halloran, and the rest of the Wash U team.

Happy weekend to all!

Sam B

Sam Bozzette, MD, PhD
Chief Medical Officer

*Immediate Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health*

*6701 Democracy Blvd., Room 926
Bethesda, MD 20892
(Use ZIP code 20817 for overnight mail or courier)
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NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

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To: Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickens]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King]; Kurilla, Michael (NIH/NCATS) [E] | (b) (6) Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] | (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Vincent, Mike | (b) (6) Bascles, Lionel | (b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry | (b) (6) Desrosiers, Betsy | (b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickens]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura | (b) (6) Srinivasan, Badhri | (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wachtel, Jonathan | (b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf], Gonzalez, Nina
| (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Jintanat Ananworan.ch | (b) (6)

Attachments: ACTIV Partnership Leadership Team Meeting 20200506 FINAL CTC WG slides.pdf; Clinical Trial Capacity Working
Group Meeting Agenda 05072020.pdf

Location: <https://zoom> (b) (6)

Start: 5/8/2020 1:00:00 PM

Show Time As: Tentative

every Tuesday and Friday from 9:00 AM to 10:00 AM

Attendees: Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak, Seema (N H/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhr; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Woodcock, Janet (FDA/CDER); Qashu, Felicia

Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Francis Collins; Gonzalez, N na, Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Criffie d, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6) Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/21/2020 2:06:49 AM
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CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan | (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rose Li Central Account | (b) (6) Lucas Smalldon | (b) (6) Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US | (b) (6)
Subject: High Level Summary and Action Items from ACTIV Therapeutics-Clinical Master Protocol Subgroup - Meeting #3
Attachments: ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 3_Key Takeaways_04202020.pdf

Dear TX-Clinical Subgroup Members,

Please find attached the quick high level summary and action items from our meeting today. Please let me know if you have any additions or amendments to these. The formal summary will follow.

The co-chairs, subgroup chair, Elizabeth, and I are hard at work getting together the materials for tomorrow's call. We will likely circulate this very late to night or in the morning, as we are still working on a few things.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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Sent: 12/16/2020 2:40:18 PM
Subject: FW: ACTIV Leadersh p Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION
Attachments: 12.16 ACTIV EC and Leadersh p Team Meeting 20201215_vF (003).pdf; 12.16 ACTIV EC and Leadership Team Meeting_APPENDIX 20201215 vF.pdf; 2020-11-19 ACTIV Leadership Team Meeting_Summary v3.pdf

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 6:29 PM
To: Wholley, David (FNIH) [T] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)>
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(FNIH) [T] <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh
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<(b) (6)> Meltzer, Abbey (FNIH) [T] <(b) (6)>
Subject: RE: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION

Dear ACTIV Leadership Team and meeting attendees:

Please see corrected version of materials. Sorry for the confusion.

Regards,

David

David Wholley

Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 5:08 PM
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 Tountas, Karen (FNIH) [T] (b) (6) >; Wachtel, Jonathan (b) (6) Wholley, David (FNIH) [T]
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 < (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) ; Wolinetz, Carrie (NIH/OD) [E]
 (b) (6) Meltzer, Abbey (FNIH) [T] < (b) (6)
Subject: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, December 16, 10:00 – 11:30 a.m. Eastern U.S. Time**. The minutes from the November 19 Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 8/26/2020 1:07:58 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Next Vaccines Working Group meeting: Friday, 14 Aug

Hi all,

Yes, I'm happy to pull this together and distribute to you.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Wednesday, August 26, 2020 8:50 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Cc: Santos, Michael (FNIH) [T] <(b) (6)>
Subject: RE: Next Vaccines Working Group meeting: Friday, 14 Aug

Thanks, Ashley. I have sent Mike a note already requesting all the minutes of this or other calls on the topic.

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, August 26, 2020 8:26 AM
To: Wholley, David (FNIH) [T] <(b) (6)>
Cc: Santos, Michael (FNIH) [T]
Subject: FW: Next Vaccines Working Group meeting: Friday, 14 Aug

This was the 8/14 meeting but I do not have any notes yet. The AZ Brazil trial did come up on the call and Katrin raised the issue of a trial receiving approval in another country and asked how would this affect trials in the US – defer to Mike for details.

From: Santos, Michael (FNIH) [T] <(b) (6)>
Sent: Friday, August 7, 2020 12:49 PM
To: (b) (6); Lowy, Douglas (NIH/NCI) [E] <(b) (6)>
Arvin, Ann <(b) (6)>; Beth Bell <(b) (6)>
Cavaleri Marco <(b) (6)>
(b) (6); Greg Glenn <(b) (6)> Haynes, Barton
(b) (6); Marks, Peter (FDA/CBER)
(b) (6) Mascola, John (NIH/VRC) [E] <(b) (6)> Messonnier, Nancy
(CDC/DDID/NCIRD/OD) <(b) (6)>; Nelson Michael <(b) (6)> Offit, Paul
(b) (6) Seals, Jonathan (OS/ASPR/BARDA) <(b) (6)>;
(b) (6) Tal Zaks <(b) (6)>
Cc: Tolman, Brett <(b) (6)> Hopps, Markay <(b) (6)>
Kozlowski, Mary (NIH/NCI) [C] <(b) (6)>; Johnson, Maureen (NIH/NCI) [E]
(b) (6) Jeneffer Haynes <(b) (6)>

(b) (6) kelli (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]
 (b) (6) ; Isabel Ramsey (b) (6) ; Parker,
 Ashley (NIH/OD) [E] (b) (6) ; Marston, Hilary (NIH/NIAID) [E] (b) (6) Qashu, Felicia
 (NIH/OD) [E] (b) (6) ; Culp, Michelle (NIH/OD) [E] (b) (6) ; Gadbois, Ellen (NIH/OD) [E]
 (b) (6) ; Wholley, David (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T]
 (b) (6) ; Menetski, Joseph (FNIH) [T] (b) (6) Adam, Stacey (FNIH) [T] < (b) (6)
 Tountas, Karen (FNIH) [T] (b) (6) ; James, Stephanie (FNIH) [T] (b) (6) ; Colvis, Christine
 (NIH/NCATS) [E] (b) (6) ; Desrosiers, Betsy (b) (6) Eric Hughes
 (b) (6) ; Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Read, Sarah (NIH/NIAID) [E]
 (b) (6) ; Young, John (b) (6) ; Paul Gillard (b) (6) ; François P
 Roman < (b) (6) Hamilton, Holli (OS/ASPR/BARDA) (b) (6) Modjarrad, Kayvon
 CIV USARMY MEDCOM WRAIR (USA) < (b) (6) ; Kathleen Neuzil
 (b) (6) ; Schrag, Stephanie (CDC/DDID/NCIRD/DBD) < (b) (6) ; Verani, Jennifer R.
 (CDC/DDID/NCIRD/DBD) (b) (6) ; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) (b) (6) ; Gonzalez,
 Nina (b) (6) ; 'Wachtel, Jonathan' < (b) (6) Stratton, Benjamin
 (b) (6) ; Margaret (b) (6)
 (b) (6) ; Bethany Stokes < (b) (6) ; Kathleen Callahan
 < (b) (6) ; Molloy, Della (DPH) < (b) (6) Jacqueline Miller
 (b) (6) ; Kayvon Modjarrad (b) (6)

Subject: Next Vaccines Working Group meeting: Friday, 14 Aug

Dear Vaccines Working Group members,

The next meeting of the Working Group will be next Friday, 14 Aug, at 1:30pm ET (10:30am PT / 7:30pm CEST) A calendar invite follows.

The agenda topic is the possibility of perceived or actual political pressure to introduce a vaccine prior to evaluation of the vaccine against the stated success criteria (or perhaps despite an apparent failure to meet those criteria), and the implications of this possibility for public confidence in vaccines.

Relevant to this topic: At today's meeting of the Vaccines Clinical Trials Sub-Group, our discussion of the potential implications of the first vaccine success included a discussion of EUA in the US. Our members from the FDA shared emphatically that an EUA decision on the first successful vaccine will require clinical efficacy data, in addition to safety and CMC data. (Subsequent evaluation of other vaccine candidates could in principle proceed through various pathways.)

We're looking forward to our meeting. Please feel free to reach out with any questions or suggestions.

Best regards,
 Brett and Mike

Michael Santos, PhD
 Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Sunday, August 2, 2020 11:01 AM
Subject: Notes from the Vaccines Working Group meeting

Dear Vaccines Working Group members,

As described in the agenda email (below), we discussed the evolution of the Vaccines Working Group at our last meeting. Please see the attached notes for a summary of the topics proposed as ongoing and future priorities for the group.

In addition, please note that the current plans for future meetings within the Working Group are:

- Vaccines Working Group: to meet as needed, determined by Kathrin and Doug (and potentially at the request of ACTIV Leadership).
- Vaccines Clinical Trials Sub-Group: to meet every other week.
- Other Sub-Groups: Not planning to meet beyond completing existing priorities, such as the vaccine-associated enhanced disease article and summary.

And one related update since the meeting: the vaccine-associated enhanced disease manuscript has been submitted; our gratitude to this group for your input, and our congratulations to the authors and especially Ann and Bart for leading this impressive contribution to this milestone.

Please reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, July 28, 2020 2:58 PM
Subject: Agenda for tomorrow's (Wednesday's) Vaccines Working Group meeting

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Wednesday) at 10am ET / 7am PT / 4pm CEST.

This week is the 16th of the Vaccines Working Group, and Francis Collins will join the start of tomorrow's meeting to recognize the progress we have made. Additionally, we have been asked by ACTIV leadership to consider how the Working Group should operate from here.

We are deeply grateful to all of you for your engagement in our collective efforts. We have identified and addressed many important topics for COVID-19 vaccine development and we have additional contributions yet to come, such as the article on vaccine-associated enhanced disease.

At this meeting we would like to discuss the topics that the group would prioritize going forward. We want to support the Working Group to continue to take on issues where we have unique value to add while adjusting the number and frequency of meetings to ensure we are being efficient with everyone's time.

Please come to the meeting with your perspective on what topics are important for the Working Group to address; in the immediate term we plan to continue conversations about the implications of the first vaccine success and of course continue with the dissemination of the vaccine-associated enhanced disease findings. **If you are unable to attend the meeting, as always your thoughts are welcome via email.**

Finally, we want to acknowledge and apologize for the overlap of tomorrow's meeting with the start of the ACIP meeting. We know some of you are directly involved with ACIP and will miss the Working Group meeting. Certainly we will wrap up as soon as our discussion is finished for those who would like to hop over to the ACIP meeting afterwards.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Saturday, July 25, 2020 5:01 PM
Subject: Notes from the Vaccines Working Group meeting

Dear Vaccines Working Group members,

Thank you for your participation in the meeting. The meeting notes and materials are attached.

We're also grateful for the feedback you have provided on the vaccine-associated enhanced disease manuscript. Ann and Bart are working through that now, and we look forward to submitting the final version soon.

We will be in touch again soon about this week's meeting (Wednesday, 10am ET), and in the meantime please feel free to reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, July 21, 2020 10:05 PM
Subject: Agenda for the Vaccines Working Group meeting

Dear Vaccines Working Group members,

We're looking forward to our meeting tomorrow (Wednesday), at 1:30pm ET (10:30am PT / 7:30pm CEST).

The agenda topics are:

- Brief update on the vaccine-associated enhanced disease manuscript
 - As a reminder, this is a product of the Working Group and all Working Group members are invited to provide feedback by Thursday at 8pm ET (see attached email sent by Brett on Monday)
- Follow-up discussion of approaches for non-specific immunity
 - Doug will lead this discussion. If you missed the discussion at last week's meeting, the notes are attached again.

As always, please let us know if you have any questions or input.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Sunday, July 19, 2020 4:04 PM
Subject: Notes from the Vaccines Working Group meeting

Dear Vaccines Working Group members,

Thank you for your participation in our last meeting, and particular thanks to Bob Gallo and Konstantin Chumakov and Paula for their presentations and discussion. Attached are the notes and slides presented.

As always, please don't hesitate to reach out with any comments or questions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Friday, July 10, 2020 11:28 PM
Subject: Agenda for the Vaccines Working Group meeting Monday

Dear Vaccines Working Group members,

We're looking forward to our next meeting, Monday at 12pm ET (9am PT / 6pm CEST). There are two agenda topics for the meeting:

- The potential for OPV to provide temporary protection against COVID-19
 - Bob Gallo and colleagues will join to discuss their concept with the group
- A recap of the discussion Thursday in the Vaccines Clinical Trials Sub-Group meeting on the implications of the first vaccine licensure on other vaccine efficacy trials

As inputs to those conversations, the notes from the Clinical Trials Sub-Group meeting are attached along with two press articles and a compendium of journal articles about the OPV concept.

Please don't hesitate to reach out with any questions or feedback.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
(b) (6) . fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6)]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W (b) (6) Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras] Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6)]; Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6)]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Draghia-Akli, Ruxandra [(b) (6) Garner, Carl [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Kim, Elizabeth [(b) (6)

CC: Gonzalez, Nina [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael

(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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| (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6)
Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T]
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| (b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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| (b) (6) Tolman, Brett | (b) (6)]; Alvarez, Rosa | (b) (6) Dana
Carluccio | (b) (6)]; Rose Li Central Account | (b) (6)]; Lucas
Smalldon | (b) (6) Stratton, Benjamin | (b) (6)
(b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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| (b) (6) Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E]
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200625_vF.pdf; RACAP_COVID-19_MAP_INSIGHTS.pdf; COVID-19_06152020_F.pdf

Start: 6/25/2020 5:00:00 PM

End: 6/25/2020 6:00:00 PM

Recurrence: (none)

Required Attendees: Draghia-Akli, Ruxandra; Garner, Carl; Stein, Peter (FDA/CDER); Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Eisner, Mark; Gottesdiener, Keith; Hughes, Enc; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Melors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschian, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylvia (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess, Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]

Dear ACTIV_TX-Clinical WG,

Please find attached the slides that we will use to update on the progress on the master protocols and antiviral prioritization in the last week.
We look forward to speaking with many of you tomorrow.

Kind regards,
Stacey

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Sent: 5/3/2020 9:45:28 PM
To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd];
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(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; hotez@bcm.edu;
(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda], Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fdb4598a57b423d484dcf9f-offit.email], HSchulte@its.nj.com;
Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se];
(b) (6) Tal Zaks [(b) (6)
CC: Tolman, Brett [(b) (6)]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj];
(b) (6) (b) (6) (b) (6) Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda],
(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Sahin@Uni-Mainz.de;
Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt];
(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras],
(b) (6) (b) (6) (b) (6)
(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis];
(b) (6) (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; (b) (6)
Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskipj], Alvarez, Rosa Maria [(b) (6)]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Kim, Elizabeth [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Stratton, Benjamin [(b) (6)
Subject: Vaccines Working Group important update: Clinical Trial plans

Dear Vaccines Working Group,

Yesterday evening there was an exciting expansion of the opportunity for the Vaccines Working Group to contribute to accelerating vaccine development. We learned that there will be US government funding for a master protocol phase 2/3 adaptive vaccine efficacy trial, with provisions to add and drop vaccine candidate arms over time.

The Clinica Trial Sub-Group (slight name change) will be tasked with supporting this master protocol trial, including the protocol and the networks/sites implementation. The goal is to have this trial ready to start by July 1, though there may be an opportunity to start in June if the work can be completed by then.

This is a significant expansion of scope for the Sub-Group. Given the magnitude of this responsibility, we will be asking for additional representation on the Sub-Group and pulling in expertise, including some of the master protocols experts that have been writing the ACTIV therapeutics protocols. The first meeting of the Sub-Group is tomorrow at 10am ET (7am PT / 4pm CEST).

We will also discuss this at the Vaccines Working Group meeting on Tuesday at 12pm ET (9am PT / 6pm CEST). Please don't hesitate to reach out with any questions.

Best regards,
Mike, for the Vaccines Working Group

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
(b) (6) fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]

Sent: 5/14/2020 9:01:45 PM

To: (b) (6) (b) (6) Tomas Cihlar | (b) (6) Pitt, Margaret L CIV
USARMY MEDCOM USAMRIID (USA) | (b) (6) (b) (6) ;
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas | (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]

CC: Diamond, Michael | (b) (6) Rodriguez, Robin D | (b) (6) Hall, Matthew (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c76a7b2623714aaaa095fda97973f5e6-hallma_b4f6]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) ; Hughes, Eric | (b) (6) Jansen, Kathryn | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n], Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria | (b) (6) Kim, Elizabeth | (b) (6) Tolman, Brett | (b) (6) Wachtel, Jonathan | (b) (6) Prabhavathi Fernandes | (b) (6) Rose Li | (b) (6) Dana Carluccio | (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel; Jonson, Samantha
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d],
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Dave Frankowski
[(b) (6) Baric, Toni C [(b) (6)]; Stratton, Benjamin
[(b) (6)

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Attachments: 2020-05-12_Precinical WG Summary RLA_d3.docx

Dear preclinical working group and invitees,

Please find the minutes from our meeting on Tuesday. I apologize for being late (my fault, I am afraid). We look forward to seeing you all tomorrow. Please let me know if you have any questions or modifications to these.

Best regards,
Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

To: (b) (6) (b) (6) Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM

USAMRIID (USA); Menetski, Joseph (FNIH) [T]; (b) (6) (b) (6)

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(b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley

(NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao,

Srinivas; Qashu, Felicia (NIH/OD) [E]

Cc: Diamond, Michael; Rodriguez, Robin D; Hall, Matthew (NIH/NCATS) [E]; Florence, Clint (NIH/NIAID) [E]; Lowy, Douglas (NIH/NCI) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Dave Frankowski; Baric, Toni C; Stratton, Benjamin

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Tuesday, May 12, 2020 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us>. (b) (6)

Holding time

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 10/27/2020 4:13:22 PM
To: (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6)]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6)]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
CC: Diamond, Michael [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user705e5647]; Kim, Elizabeth [(b) (6)]; btoiman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan [(b) (6)]; Prabhavathi

Fernandes | (b) (6) Rose Li | (b) (6) Dana Carluccio
 | (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
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 | (b) (6) Dave Frankowski | (b) (6) Baric, Toni C
 | (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; Stratton, Benjamin
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188];
 Gadbois, El en (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
 Mason, Stephen | (b) (6) (b) (6) Connelly, Sarah
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab];
 (b) (6)

Subject: ACTIV Preclinical full working group

Dear Preclinical working group,

Next week's ACTIV EC meeting (Nov 4th) has been scheduled on top of our full working group meeting. It is important for us to talk, especially after the EC meeting, so I was hoping we can move this to either.

Option A: 11-12 Wed, Nov 4, 2020

Option B: 10-11 Thur, Nov 5, 2020

Can you please let me know which of these options work for you. I will move the meeting to the most popular option.

Best regards,

Joe

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6) , fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/2/2020 2:29:00 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: Update on other COVID "master protocol" efforts

This is indeed a cause for serious concern. See my note about a conversation I had with Gary Gibbons yesterday, and the need to bring NHLBI back into the tent.

Do I need to have the same conversation with Walter Koroshetz?

FC

From: Wholley, David (FNIH) [T] < > (b) (6)
Sent: Friday, May 1, 2020 7:12 PM
To: Collins, Francis (NIH/OD) [E] < > (b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] < > (b) (6)
Subject: Update on other COVID "master protocol" efforts

Hi Francis,

I sat in on several of the Working Group calls today and had my daily update with my team and one with Deloitte. I learned:

- The VA is working on a master protocol for COVID; Margaret Anderson thinks Mike Milken is behind this. Karen Tountas has arranged for our VA rep on the Clinical Trial Capacity Group, Victoria Davey, to set up a call with the VA MP folks and the ACTIV MP design Sub Group Stacey Adam is leading.
- From a presentation that Mike Poole of Gates Foundation gave us, their Tx Accelerator is arranging reasonably robust testing of many of the compounds we are looking to prioritize for ACTIV, including to our surprise mAbs. We still see daylight, but differentiation will be that much more challenging.
- NHLBI is actively designing an MP in their PETAL network for anticoagulants. Thanks to Cliff Lane, we are trying to get Amy Patterson to speak to Sarah Read and Stacey so we have some chance to decently align approaches.
- NINDS is both collaborating with NHLBI and running their own protocol using their SIREN network.

We cannot control what Milken and Gates do, but it is distressing to see efforts announced within NIH that more or less completely overlap and potentially compete for the same kinds of protocols and patients that ACTIV is attempting to address. It makes the partnership overall look disorganized. In fact one of our WG co-chairs used the chat feature on Zoom to comment on the side to one of my folks during a description of one of the other side NIH institute efforts that "this is like a circus—how do these people not talk to each other?"

This is not good. While you have my commitment that we will always do what we can to make sure we communicate to others in NIH the ACTIV plans, we are going to lose control of the public narrative overall if this continues. I think there is still time to address this; I would suggest a way be found to bring these other efforts together under the ACTIV banner and brand as soon as possible.

Regards,
David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNHI earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 6/11/2020 7:38:52 PM
To: (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
(b) (6) : (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
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(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar (b) (6) ; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Diamond, Michael (b) (6) ; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy (b) (6) Hughes, Eric (b) (6) Jansen, Kathryn (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T]

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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria
 [(b) (6)]; Kim, Elizabeth [(b) (6)]; Tolman, Brett [(b) (6)]; Wachtel,
 Jonathan [(b) (6)]; Prabhavathi Fernandes [(b) (6)]; Rose Li
 [(b) (6)]; Dana Carluccio [(b) (6)]; Lagos, Enrique (NIH/NCATS)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
 [(b) (6)]; Dave Frankowski [(b) (6)]; Baric, Toni C
 [(b) (6)]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
 [(b) (6)]

Subject: ACTIV Preclinical full working group

Location: <https://fnih.zoom.us/j/91811111111> (b) (6)

Start: 6/17/2020 2:00:00 PM

End: 6/17/2020 3:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
 every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
 (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];
 Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];
 Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]

Optional Attendees: Culp, Michelle (NIH/OD) [E]; Gadbors, Ellen (NIH/OD) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin,
 Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy;
 Hughes, Eric; Jansen, Kathryn; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E];
 Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez,
 Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio;
 Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C];
 Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E];
 Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://fnih.zoom.us/j/91811111111> (b) (6)

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Sent: 11/23/2020 4:33:43 PM
Subject: FW: Notes from Thursday's ACTIV Leadership Team Meeting
Attachments: 2020-11-19_ACTIV_Leadership_Team_Meeting_Summary_v3.docx

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Monday, November 23, 2020 11:18 AM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane
<(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]
<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
Victoria Davey <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael
<(b) (6)> Erbeling, Emily (NIH/NIAID) [E] <(b) (6)> Erck, Stan
<(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Freire, Maria (FNIH) [T]
<(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E]
<(b) (6)> Hudson, Thomas <(b) (6)> James, Stephanie (FNIH) [T]
<(b) (6)> Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> Kramer, Lynn
<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Lepore, John <(b) (6)>
Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary (NIH/NIAID) [E] <(b) (6)>
Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David <(b) (6)> Menetski, Joseph
(FNIH) [T] <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh
<(b) (6)> Pangalos, Mene <(b) (6)> Pao, William
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Paul, Steve <(b) (6)>
Perlmutter, Roger <(b) (6)> Plenge, Robert <(b) (6)> Plump, Andy
<(b) (6)> Rachel Ramoni <(b) (6)> Reed, John <(b) (6)> Reese,
David <(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)>
Skovronsky, Daniel <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul
<(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Talley, Michael
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<(b) (6)> Young, John <(b) (6)> Colvis, Christine (NIH/NCATS) [E]
<(b) (6)> Desrosiers, Betsy <(b) (6)> Eric Hughes
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>
Young, John <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)>
Carluccio, Dana <(b) (6)> Castillejos, Carlos <(b) (6)> FNIH Central Account
<(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Hallett, Adrienne (NIH/OD) [E]
<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E]
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<(b) (6)> Gorman, Greta (FNIH) [T] <(b) (6)> Meltzer, Abbey (FNIH) [T]
<(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E]
<(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Margaret Anderson
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Benjamin <(b) (6)> btolman <(b) (6)> : Tountas, Karen (FNIH) [T]
<(b) (6)> Wachtel, Jonathan <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Subject: Notes from Thursday's ACTIV Leadership Team Meeting

Dear Leadership Team members and meeting attendees:

Please see the notes from our teleconference this past Thursday, November 19. Please let me know any additional comments, questions, or suggestions regarding these notes or the action items.

Thank you again for all your support of and contributions to ACTIV.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/1/2020 3:19:09 AM
To: Eric Hughes | (b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli | (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Na mish Patel | (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike | (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael | (b) (6) Keith Gottesdiener (b) (6) Elliott Levy | (b) (6) Wung, Peter /US | (b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner | (b) (6)
CC: Elizabeth Kim | (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria | (b) (6) Salathin, Carla | (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon | (b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

Dear TX-Clinical Agent Prioritization Subgroup,

Thank you once again for a productive meeting.

I have heard from a few of you that as we discussed in the meeting you may need a little more time that until tomorrow due to the additional agents. **Therefore, we are extending the deadline for scoring until 12pm ET on Sunday, May 3.** We really cannot extend it further due to needing have a determination for an ACTIV Leadership Meeting early next week, so I would ask that everyone try to meet that deadline punctually.

I hope this will help with a little breathing room for scoring.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: (b) (6) Mobile: (b) (6)

From: Adam, Stacey (FNIH) [T]

Sent: Thursday, April 30, 2020 7:05 PM

Subject: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

Importance: High

Dear TX-Clinical Agent Prioritization Subgroup,

I appreciate the candid and productive meeting that we had today. All your feedback is very helpful to refine our process for the next time.

For all of you working on scoring right now, please find attached a number of pieces of information that maybe helpful. Some if this some of your groups may have received before, however, I wanted to share it with the whole group for transparency and for having all of our reference data in one place. The information you will find attached is:

1. The summary spreadsheets for the agents in the host targeted category that have been added from the R&D Consortium group + 1 for Firazyr as it was requested. (one note, the group shared with us Firazyr is likely be tested in a few other trials, so that may need to be considered)
2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the front lines. These were previously shared with the Symptomatic/Supportive therapy group.
3. An article relevant to immune modulator use in COVID-19.
4. Articles for the Antiviral group on some preclinical testing work.
5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access to more screening data, which should contain all but EIDD-2801.
 - a. *"All of these compounds except EIDD-2801 are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here <https://reframedb.org/assays/A00440> You can create an account for free and search the data."*

Please find attached the updated spreadsheet with all the new relevant compounds added for the groups to vote on. These new compounds for your groups are highlighted in green.

Finally, please find below the captured action items and key takeaways from the meeting

Action Items

Action Items		
	Information	POC
1	Provide Review Committee members with 5 compounds for review, along with factsheets from the R&D Consortium	Keith Gottesdiener & Elliott Levy /
2	Send updated score sheets Agent Prioritization Review Committee members (immunomodulators) score additional agents that have been added from the R&D Consortium list	Stacey Adam Stacey Adam
3		AP Sub Group Members

Getting standardized, reliable data on the agents

4

- Trans-NIH information, intramural and extramural
- Mike Poole, Gates Foundation

Stacey Adam /

Ruxandra Draghia-Akli

5

Ask Preclinical Working Group (R&D members) for relevant data on agents if available

Joe Menetski

6

Get data on antivirals from NIAID and NCATS

Sarah Read/Christine Colvis

Key Takeaways

- We are re-evaluating our list for scoring and adding other agents that were inadvertently left out
- We will not go back and re-evaluate the triage list.
- Sub Group Members voicing concern on lack of confidence in agents they've had to score. More research needed on drugs to understand whether these are worth putting into clinical trials. Need for more data.
- Suggested need to understand value of the agents we are evaluating over remdesivir

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) Mobile:(b) (6),
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/17/2020 12:42:08 PM
To: Jim Neaton [(b) (6)]; Jens Lundgren [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Srinivasan, Badhri [(b) (6)]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Victoria Davey [(b) (6)]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f97a421-Marina.Koza]; Tierney, John (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rachel Harrigan [(b) (6)]; Erhardt, William (OS/ASA/OCIO/DCIO-Ops) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Gelijns, Annetine [(b) (6)]; Mark Polizzotto [(b) (6)]; Ginny Kan [(b) (6)]; Baker, Jason [(b) (6)]; Roger Paredes [(b) (6)]; Thompson, Taylor, M.D. [(b) (6)]; Babiker, Ab [(b) (6)];
CC: Chen, Helen Q. [(b) (6)]; Wachtel, Jonathan [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A. [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurila]; Kenny, Dermot [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; Pett, Sarah [(b) (6)]; Grace, Beth (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Barrett, Kevin (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrett2]; Denning, Eileen [(b) (6)]; Baseler, Beth (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2363525c118a468b9e8f5f61707c63f5-bbaseler]; Engel, Theresa (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e86305ea82754e65b67a63591ed867ba-engelt]; Lisbeth Jørgensen [(b) (6)]; RH-FP-INSIGHT014-ACTIV3 [(b) (6)]

Subject: ACTIV-3 Operations Team Meeting

Location. <https://fnih.zoom.us> (b) (6)

Start: 6/23/2020 3:00:00 PM

End: 6/23/2020 4:00:00 PM

Show Time As. Tentative

Required Attendees: Jim Neaton; Jens Lundgren; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Higgs, Elizabeth (NIH/NIAID) [E]; Srivivasan, Badhri; Goff, David (NIH/NHLBI) [E]; Nayak, Seema (NIH/NIAID) [E]; Victoria Davey; Kozak, Marina (OS/ASPR/BARDA); McNay, Laura (NIH/NIAID) [E]; Tierney, John (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; Erhardt, William (OS/ASA/OCIO/DCIO-Ops) (CTR); Reineck, Lora (NIH/NHLBI) [E]; (b) (6) Geijns, Annetine; Mark Polizzotto; Ginny Kan; Baker, Jason; Roger Paredes; Thompson, Taylor, M.D.; Babiker, Ab

Optional Attendees: Chen, Helen Q.; Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Kenny, Dermot; Parker, Ashley (NIH/OD) [E]; Pett, Sarah; Grace, Beth (NIH/NIAID) [C]; Barrett, Kevin (NIH/NIAID) [E]; Denning, Eileen; Eileen Denning; Baseler, Beth (NIH) [C]; Engel, Theresa (NIH) [C]; Lsbeth Jørgensen; RH-FP-INSIGHT014-ACTIV3

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From: Menon, Sandeep M [(b) (6)]
Sent: 5/14/2020 5:30:09 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Re: [EXTERNAL] Time sensitive: Making your ACTIV Participation Public

Hi Francis

Thanks for checking. I am fine to be included.

Sandeep

Sandeep Menon, PhD, MPH
Senior Vice President and Head of Early Clinical Development, Pfizer Inc
1 Portland Street, Cambridge, MA 02139, USA
Cell: (b) (6)
Email: (b) (6)

From: "Collins, Francis (NIH/OD) [E]" < (b) (6) >
Date: Thursday, May 14, 2020 at 11:00 AM
To: "Collins, Francis (NIH/OD) [E]" < (b) (6) >
Cc: "Myles, Renate (NIH/OD) [E]" < (b) (6) > "Meltzer, Abbey (FNIH) [T]" < (b) (6) > "Wholley, David (FNIH) [T]" < (b) (6) >
Subject: [EXTERNAL] Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/16/2020 10:24:23 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Butterson, Joan (b) (6)]; Collins, Sylvia (FDA/CDER) (b) (6) Judy Currier (b) (6) De Claro, R. Angelo (FDA/CDER) [(b) (6) Mark Eisner | (b) (6) Keith Gottesdiener [(b) (6) Eric Hughes | (b) (6) LaVange, Lisa M. (b) (6) Elliott Levy [(b) (6) Sandeep Menon | (b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] | (b) (6) Read, Sarah (NIH/NIAID) [E] | (b) (6) Amanda Peppercorn | (b) (6)]; Price, Dionne (FDA/CDER) | (b) (6) Rubin, Daniel B. (FDA/CDER) | (b) (6) Shen, Yuan Li (FDA/CDER) | (b) (6) Farley, John (FDA/CDER) (b) (6)]; Goff, David (NIH/NHLBI) [E] | (b) (6) Vincent, Michael | (b) (6)
CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] | (b) (6) Wachtel, Jonathan (b) (6) Elizabeth Kim [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Rose Li Central Account [(b) (6) Lucas Smalldon | (b) (6) Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] | (b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Wung, Peter /US | (b) (6)

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #4

Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_21Apr2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting Agenda_04212020.pdf; D. Goff network capacity template_04202020.xlsx; ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 3 Key Takeaways_04202020.pdf

Location: <https://fnih.zoom>. (b) (6)

Start: 4/21/2020 5:00:00 PM

End: 4/21/2020 6:00:00 PM

Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylvia (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

Dear ACTIV TX-Clinical Master Protocol SG,

Please find attached the materials for today's call. Apologies for the slight delay in sending.

1. Agenda
2. Slides for Discussion – Updated Timelines for feedback and then questions to consider for the two master protocols to start deciding design.
3. Clinical Trial Network Survey – the CTC WG would like any feedback we might have about other needed information.
4. High level update from yesterday

We look forward to speaking with you today.

Thanks,
Stacey

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From: Florence, Clint (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E032D0BC8554E8787E844A7773295FE-FLORENCEWC]
Sent: 1/21/2021 6:34:14 PM
To: Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
(b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Ames, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 | (b) (6) Diamond, Michael | (b) (6) Rose Li
 | (b) (6) Dana Carluccio | (b) (6) Lagos, Enrique (NIH/NCATS)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel]; Jonson, Samantha
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
 Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 | (b) (6) Dave Frankowski | (b) (6) antoinette_baric
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy,
 Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
 Mason, Stephen (b) (6) caroline (b) (6) (b) (6)
 Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Loyd
 | (b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

Hello All –

Quick update on variants and BEI.

(b) (4)

Thanks --

Clint

From: Connelly, Sarah <(b) (6)>
Sent: Thursday, January 21, 2021 1:19 PM
To: Menetski, Joseph (FNIH) [T] <(b) (6)> Hild, Sheri (NIH/OD) [E] <(b) (6)>
david. <(b) (6)> Baric, Ralph <(b) (6)> john. <(b) (6)> Ottinger,
(b) (6) Elizabeth (NIH/NCATS) [E] <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)>
Hewitt, Judith (NIH/NIAID) [E] <(b) (6)> Deming, Damon (FDA/CDER) <(b) (6)>
<(b) (6)> Cat. <(b) (6)> Parker, Ashley (NIH/OD) [E]
<(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Adams, Peter (OS/ASPR/BARDA) <(b) (6)> Rao, Srinivas <(b) (6)> Qashu, Felicia
(NIH/OD) [E] <(b) (6)> Tomas Cihlar <(b) (6)> Pitt, Margaret L CIV USARMY
MEDCOM USAMRIID (USA) <(b) (6)> Punturieri, Antonello (NIH/NHLBI) [E]
<(b) (6)> Charette, Marc (NIH/NHLBI) [E] <(b) (6)> Fessel, Josh (NIH/NHLBI) [E]
<(b) (6)> Cc: Wholley, David (FNIH) [T] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)>
Melencio, Chery: (FNIH) [T] <(b) (6)> Desrosiers, Betsy <(b) (6)> Eric Hughes
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>
Tountas Karen (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T]
<(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Prabhavathi Fernandes
<(b) (6)> Diamond, Michael <(b) (6)> Rose Li
<(b) (6)> Dana Carluccio <(b) (6)> Lagos, Enrique (NIH/NCATS) [E]
<(b) (6)> Jonson, Samantha (NIH/NCATS) [E] <(b) (6)> Gonzalez, Nina
<(b) (6)> Simon, Dina (NIH/OD) [C] <(b) (6)> Burrus-Shaw, Cyndi (NIH/OD) [E]
<(b) (6)> Rodriguez, Robin D <(b) (6)> Dave Frankowski
<(b) (6)> antoinette_baric <(b) (6)> Lowy, Douglas
(NIH/NCI) [E] <(b) (6)> Florence, Clint (NIH/NIAID) [E] <(b) (6)> Nancy Haigwood
<(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E]
<(b) (6)> Hawk, Harrison <(b) (6)> Mason, Stephen <(b) (6)>
<(b) (6)> Lumsden, Joanne (NIH/NCATS) [C]
<(b) (6)> K C Kent Lloyd <(b) (6)>
Subject: RE: ACTIV Preclinical full working group

Dear Preclinical Working Group,

Thank you all for attending our ACTIV preclinical full working group meeting yesterday. Please see attached for the notes from our discussion, and let us know if you all have any additions or amendments. We have also attached a slide with the subgroup updates we didn't get to during the meeting.

Also attached please find the finalized report for the SARS-CoV-2 summit on antiviral drug development. Sharing with the WG for awareness.

Best Regards,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP

GADB0000003935-2517671

Tel/Direct: (b) (6)
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-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] < (b) (6) >

Sent: Friday, October 2, 2020 2:19 PM

To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E];

(b) (6)

(b) (6)

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; Baric, Ralph;

(b) (6)

Ottinger, Elizabeth (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith

(NIH/NIAID) [E]; Deming, Damon (FDA/CDER);

(b) (6)

Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];

(b) (6)

Adams, Peter

(OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM

USAMRIID (USA), Panturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E], Fessel, Josh (NIH/NHLBI) [E];

(b) (6)

Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Eric

Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas,

Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria;

Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio;

Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-

Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E];

Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James

(NIH/OD) [E]; Hawk, Harrison; Mason, Stephen;

(b) (6)

Connelly, Sarah;

(b) (6)

Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd;

(b) (6)

Subject: ACTIV Preclinical full working group

When: Wednesday, January 20, 2021 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us>.

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Changing time for preclinical WG

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 2/25/2021 5:54:47 PM
To: Levy, Eliot [(b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc8c847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Philips, L Revell CIV DTRA RD (USA) | (b) (6) Petrovick, Martha - 0449 - MITLL | (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Larry Tsai | (b) (6) Wung, Peter K | (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin | (b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John | (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]; Salathin, Carla | (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski]; Dana Carluccio | (b) (6) Rose Li Central Account | (b) (6) Lucas Smalldon | (b) (6) ; | (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, H lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Hoots, W Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) | (b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Embry, A an (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]

Subject: ACTIV Therapeutics-Clinical Working Group

Attachments: ACTIV_TX-Clinical WG Meeting_20210225_v1.pdf

Location: <https://fnih.zoom.us>, (b) (6)

Start: 2/25/2021 6:00:00 PM

End: 2/25/2021 7:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Levy, Elliott; Bozzette, Sam (NIH/NCATS) [E]; Butters, Joan; De Ciaro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra, Gottesdiener, Keith, Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Mellors, John, Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Prosch, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylvia (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Wung, Peter K

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla, Menetski, Joseph (FNIH) [T]; Dana Carluccio; Rose Li Centra Account; Lucas Sma Idon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex David; Lumsden, Joanne (NIH/NCATS) [C]; Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting. See you in a few minutes.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 8/29/2020 2:28:28 AM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fid]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesdener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn | (b) (6) Garner, Carl | (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner | (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae0627d74e3cbd894e30160869f0-jbeigel]; Philips, L Revell CIV DTRA RD (USA) | (b) (6) Petrovick, Martha - 0449 - MITLL | (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n], Young, John (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]; Salathin, Carla | (b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa | (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio | (b) (6)]; Rose Li Central Account (b) (6)]; Anderson, Margaret | (b) (6) Lucas Smalldon | (b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188], (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, H lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. | (b) (6)]; Wung, Peter /US | (b) (6)]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) | (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]

Subject: Summary of the ACTIV Therapeutics-Clinical Working Group Meeting 08/28/2020

Attachments: 2020-08-27_TX-Clinical_WG_Meeting_Summary.pdf

Dear ACTIV Therapeutics-Clinical WG,

Please find attached the summary for our meeting yesterday. As a reminder, please consider ideas and topics for the manuscripts that we would like to prepare about our efforts.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/13/2020 8:19:23 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Follow-up from 1st Meeting of COVID PPP Therapeutics-Clinical Working Group - RAPID RESPONSE REQUESTED

Hi Stacey,

It's nice to meet you via email! Please keep me on both groups as I will be tracking items for Dr. Collins. I remain flexible regarding the time windows and defer to what works best for the WG members.

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to Acting Chief of Staff to the NIH Director
Office of the Director | National Institutes of Health
Tel: (b) (6)



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From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Monday, April 13, 2020 3:23 PM
To: Bozette, Sam (NIH/NCATS) [E] <(b) (6)> Butterson, Joan <(b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)> Draghia-Akli, Ruxandra <(b) (6)> Eisner, Mark <(b) (6)> Gottesdiener, Keith <(b) (6)> Hughes, Eric <(b) (6)> Judy Currier <(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa <(b) (6)> Levy, Elliot <(b) (6)> Mellors, John W <(b) (6)> Menon, Sandeep <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Patel, Naimish <(b) (6)> Peppercorn, Amanda <(b) (6)> Poole, Mike <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Cc: Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Young, John <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> Biggs, Mary <(b) (6)> Butcher, Tina <(b) (6)> Demarcus <(b) (6)> Macone, Erin <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Salathin, Carla <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Kim, Elizabeth <(b) (6)> Wachtel, Jonathan <(b) (6)> Tolman, Brett <(b) (6)> Alvarez, Rosa <(b) (6)> Gonzalez, Nina <(b) (6)>
Subject: Follow-up from 1st Meeting of COVID PPP Therapeutics-Clinical Working Group - RAPID RESPONSE REQUESTED
Importance: High

Dear ACTIV Therapeutics-Clinical WG,

Thank you all for a very productive discussion today. We appreciate all of you taking the time to join the meeting.

As discussed on the call today, I am reaching out to ask for volunteers for each of the two main sub-groups for our WG:

1. Agent Prioritization Process, Criteria, and Initial Agent List
2. Development of COVID Master Protocols

Please send me your availability to participate and your preference for which sub-group you would like to join. In addition, please send your preferred time windows or any restricted times over the next two days. Please send me this information by no later than 10 pm US ET today if you can. This will allow us to plan the meetings rapidly for Tuesday and Wednesday.

We will be working to get together agendas and will share them as they come together.

In addition to sending the information above, Tim Buchman from BARDA asked me to share the attached materials and the thoughts below for consideration on our use of the ARDS terminology.

A Remark on Terminology: "ARDS" as an expression of COVID-19

Contemporary respiratory distress syndromes were unknown until the 1960s. Prior to the invention and diffusion of mechanical ventilators following the polio epidemics of the 1950s, patients simply succumbed to severe pneumonia.

In 1967, David Ashbaugh, Tom Petty and others reported a case series of a dozen patients who experienced severe respiratory illness with chest radiographs similar to what would be observed in congestive heart failure but without the heart failure (pdf attached). The lungs simply leaked fluid.

The history of that report is summarized by Levine (one of the authors of the 1967 report) and is also attached.

Pertinent to the next half century of ARDS are the following:

- (a) "ARDS" was recognized as a final common pathway to diverse insults including (but not limited to) trauma, pancreatitis, pneumonia, and anatomically distant sepsis;*
- (b) development of a standard supportive strategy namely "lung protective, low-tidal volume ventilation" that emerged from ARDSNET (see <https://www.nejm.org/doi/full/10.1056/NEJM200005043421801>) but in fact simply reflected normal tidal volumes across all mammals, see figure 1 in the Tenney and Remmers 1963 paper, pdf attached.*

(c) a contemporary definition of ARDS that focuses almost exclusively on the extent of hypoxemia without attention to the defect in diffusion of oxygen across the alveolar-capillary membrane (the Berlin criteria, pdf attached).

Thus until 2020, ARDS accumulated underlying pathogeneses. As a consequence, treatment focused on "greatest good for greatest number". Whilst address of the underlying cause has always been part of ARDS treatment, the ventilator support regimen has been largely "one size fits most".

SARS-CoV-2 has changed the landscape. A single pathogen has affected populations of diverse heritable and acquired underlying pulmonary conditions. The pathophysiologic responses to the pathogen are partitioning into several endotypes. This has prompted both experts and pundits to call for a revision of the "one size fits most" into more tailored approaches. See the Gattinoni pdf published a couple of weeks ago in the ATS journal (pdf attached.)

There is a manuscript from John Marini and Gattinoni that will run in one of the journals I edit in the near future focusing on how ventilators injure vulnerable lungs. Luciano Gattinoni has separately contacted one of my Associate Editors to write a piece for the other journal that I edit. Suffice it to say that the conversation about partitioning treatment into approaches that reflect the expression of COVID-19 could well be part of the presentation.

I share all of the above information simply to highlight the fact that convolving the pulmonary injury consequent to SARS-CoV-2 with the term "ARDS" brings a half-century of knowledge—and also of baggage—to the therapeutics conversation. Perhaps we should be as careful and specific in the terms we choose to describe the pulmonary injury as we should be in testing candidate therapies

Our choice of words, like our choice of drugs, matters.

Tim

Timothy G. Buchman, PhD, MD
Senior Advisor
IPA to the DRIVE (Division of Research, Innovation and Ventures)
Biomedical Advanced Research and Development Authority (BARDA)
Office of Assistant Secretary for Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (HHS)

Thank you all in advance for your timely responses.

Thanks,
Stacey

Stacey J. Adam, PhD
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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 6/6/2020 6:06:14 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

It obviously went very well. Great not to have to reinvent this particular wheel, and nice that Francis and Janet will provide the "muscle."

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Saturday, June 6, 2020 1:01 PM
To: Menetski, Joseph (FNIH) [T] <(b) (6)>; Collins, Francis (NIH/OD) [E] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>; Melencio, Cheryl (FNIH) [T] <(b) (6)>; Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Hi Joe and Francis,

Did not receive anything ahead of time. This was planned on such short notice. We did not have time to get something from her, but I can give both these mAb criteria that they shared with our WG.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) Mobile: (b) (6)

From: Menetski, Joseph (FNIH) [T] <(b) (6)>
Sent: Saturday, June 6, 2020 12:55 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>; Adam, Stacey (FNIH) [T] <(b) (6)>; Melencio, Cheryl (FNIH) [T] <(b) (6)>; Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Not that I can see.

Did anyone else get any, David?

Joe

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Saturday, June 6, 2020 12:53 PM
To: Menetski, Joseph (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> ; Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

OK. Did we get any read-ahead material from Jacqueline?

From: Menetski, Joseph (FNIH) [T] <(b) (6)>
Sent: Saturday, June 6, 2020 12:53 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> > Wholley, David (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> > Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)> >
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear Francis,

The meeting has these invites.

Wholley, David (FNIH) [T]
Adam, Stacey (FNIH) [T]
Menetski, Joseph (FNIH) [T]
Jacqueline Kirchner
Woodcock, Janet (FDA/CDER)
Collins, Francis (NIH/OD) [E]

joe

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Saturday, June 6, 2020 12:50 PM
To: Wholley, David (FNIH) [T] <(b) (6)> ; Menetski, Joseph (FNIH) [T] <(b) (6)> ; Adam, Stacey (FNIH) [T] <(b) (6)> > Melencio, Cheryl (FNIH) [T] <(b) (6)> ; Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Cc: Menetski, Joseph (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Sincere apologies, I just saw this message. I don't know who has been invited to join this call, can someone fill me in?

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Saturday, June 6, 2020 7:21 AM
To: Menetski, Joseph (FNIH) [T] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> > Melencio, Cheryl (FNIH) [T] <(b) (6)> ; Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Cc: Menetski, Joseph (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: Re: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

I noticed a label on today's call "data shared in confidence". Does this give us pause in terms of inviting additional experts?

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From: Menetski, Joseph (FNIH) [T] (b) (6)
Sent: Friday, June 5, 2020 6:43:53 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T] (b) (6) >; Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear Francis,

Stacey and I have polled our working groups, asking for suggestions and volunteers that could provide expert opinion on monoclonal antibody testing during conversations with Skip Virgin and Jacqueline Kirchner. The groups are very enthusiastic about this topic and we received almost 30 names of experts in the field. Given the time frame that we are asking for people to join these calls, I have picked 4 people that are already involved in ACTIV to invite to the Jacqueline Kirchner call tomorrow and 6 to invite to the call with Skip on Monday.

As I said, there were many more, but I think we would want to talk to them first, before bringing them into a discussion like this.

I am happy to invite these folks tonight, if it would be easier and agreeable to you (I would cc you). Or I have drafted a short email for you to send them below (as always, feel free to modify).

Best regards,
Joe

Memo: ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear xx,

The NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership is setting up protocols to assess monoclonal neutralizing antibodies as therapies against COVID-19. During discussions with the ACTIV Leadership Team and in collaboration with the upcoming Monoclonal Antibody Round Table, we have a meeting to gather additional expert opinion on the appropriate preclinical testing approaches, particularly for choosing mixtures or cocktails of neutralizing Abs. I would like to have your input in the important topic during a meeting [tomorrow at 1pm ET; or Monday at 2 45pm ET]. I realize this is short notice, but the ACTIV program is moving very fast and our rapid response is essential. I hope you can join me in this important discussion.

Sincerely,
Francis Collins

Names and emails below.

Saturday call with J Kirchner:

Peter Adams, (OS/ASPR/BARDA); (b) (6)
Michael Diamond at Washington University at St Louis; (b) (6)
Kara Carter at EvoTec; (b) (6)
John W Mellors at University of Pittsburgh; (b) (6)

Monday call with Skip Virgin:

Peter Adams, (OS/ASPR/BARDA); (b) (6)

Michael Diamond at Washington University at St Louis; (b) (6)
Kara Carter at EvoTec; (b) (6)
John W Mellors at University of Pittsburgh; (b) (6)
Randall Tressler, (NIH/NIAID); (b) (6)
Sebastian Breuer, Roche; (b) (6)

Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6) | fnih.org

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From: Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 4/21/2020 7:53:44 PM
To: (b) (6) ; (b) (6) ; (b) (6) ; (b) (6) Baric, Ralph
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US
(b) (6)]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
[(b) (6) Hughes, Eric] (b) (6) Jansen, Kathryn
[(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria
[(b) (6) Kim, Elizabeth] (b) (6) Tolman, Brett] (b) (6) Wachtel,
Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael
[(b) (6) Rose Li] (b) (6) Dana Carluccio
[(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses];
Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D

(b) (6) Dave Frankowski (b) (6)

Subject: ACTIV Preclinical working group (Friday meeting)

Location: <https://fnih.zoom.us> (b) (6)

Start: 4/30/2020 3:00:00 PM

End: 4/30/2020 4:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Fr day from 11:00 AM to 12:00 PM

Required Attendees: (b) (6) (b) (6) ; (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathryn; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li, Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, N.na; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski

Request to move due to holiday

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Password: (b) (6)

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/11/2020 2:32:47 AM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
Subject: RE: slides from today and ACTIV Vaccine Committee

That would be great.

From: Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
Sent: Sunday, May 10, 2020 10:32 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Subject: Re: slides from today and ACTIV Vaccine Committee

I can join if you would like me to.

From: Francis Collins <(b) (6)>
Date: Sunday, May 10, 2020 at 10:25 PM
To: "Santos, Michael (FNIH) [T]" <(b) (6)> "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)>, "Wholley, David (FNIH) [T]" <(b) (6)>, "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)>
Subject: RE: slides from today and ACTIV Vaccine Committee

I can probably make that work. Please send information about how to link in.

From: Santos, Michael (FNIH) [T] <(b) (6)>
Sent: Sunday, May 10, 2020 10:09 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Subject: RE: slides from today and ACTIV Vaccine Committee

Hi Francis,

I have a regularly scheduled call with Kathrin and Doug at 11:15-11:45am tomorrow (Monday) morning. If you can be free then and would like to join, that's an option. If that doesn't work, we can find another time before the Wednesday meeting (1pm).

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Tabak, Lawrence (NIH/OD) [E] (b) (6)
Sent: Sunday, May 10, 2020 10:00 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) >, Wholley, David (FNIH) [T] < (b) (6) ; Santos, Michael (FNIH) [T] < (b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6)
Subject: Re: slides from today and ACTIV Vaccine Committee

Francis

Despite the reassurance on the call today that the issues have been socialized with the WG, I recommend that we do have a separate discussion with them. We should do everything possible to make this transition as smoothly as possible.
Larry

From: Francis Collins (b) (6)
Date: Sunday, May 10, 2020 at 9:52 PM
To: "Wholley, David (FNIH) [T]" (b) (6) , "Santos, Michael (FNIH) [T]" < (b) (6)
"Tabak, Lawrence (NIH/OD) [E]" < (b) (6) . "Lane, Cliff (NIH/NIAID) [E]"
< (b) (6)
Subject: FW: slides from today and ACTIV Vaccine Committee

See slides and note from Larry Corey.

Do we need a separate discussion with the Vaccines WG before their Wednesday meeting?

FC

From: Corey MD, Larry < (b) (6)
Sent: Sunday, May 10, 2020 9:35 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: slides from today and ACTIV Vaccine Committee

Francis , here are this morning's slides . As John articulated on the phone he and I have had frequent communication with Doug ; debriefing each week for an hour just the three of us . Last Thursday, we have outlined the strategy for the recently composed Clinical Development subcommittee of the Vaccine Committee . I lead this subcommittee with Paula Annunziato from Merck . Paula and I had an hour talk Saturday night (yes a zoom date) to go through the agenda for this Wednesday's upcoming call . We will be sending everyone the Science article we wrote coming out Monday as background. We will then outline the goals of the clinical development and then move to discussing key harmonized elements ; et them all interact . on key issues mainly the endpoints , populations , and we will raise the issue of the common DSMB and their ability to send suggestions to Doug and you .. We expanded the subcommittee so that all the Pharma companies on the BARDA list are represented so they will be a part of the process . Paula is a big fan of the harmonized design ; she voices the issue all Pharma companies have in a real viable market ; they don't want head to head comparisons ; parallel universes is how they always operate .
The global strategy and the link to WHO are my next on the plate issues perhaps worth a chat.
If there are other issues of concern just call My cell is (b) (6) .
Thanks Larry

From: Chen, Helen Q. [(b) (6)]
Sent: 6/26/2020 6:42:30 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Draghia-Akli, Ruxandra [(b) (6)]; Garner, Carl [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Eisner, Mark [(b) (6)]; Gottesdiener, Keith [(b) (6)]; Hughes, Eric [(b) (6)]; Judy Curner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)]; LaVange, Lisa [(b) (6)]; Levy, Eliot [(b) (6)]; Mellors, John W. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6)]; Poole, Mike [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbcb847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (N.H/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboise]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6)]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]

CC. Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6)]; Jansen, Kathrin [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6)]; Biggs, Mary [(b) (6)]; Butcher, Tina [(b) (6)]; Demarcus [(b) (6)]; Macone, Erin [(b) (6)]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [(b) (6)]; Tolman, Brett [(b) (6)]; Alvarez, Rosa Maria [(b) (6)]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6)]; Rose Li Central Account [(b) (6)]; Anderson, Margaret [(b) (6)]; Lucas Smalldon [(b) (6)]; Stratton, Benjamin [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Wung, Peter /US [(b) (6)]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]

Subject: Antiviral Candidate Contacts Request

Attachments: ACTIV Antivirals Candidates - Contacts Request (003).xlsx

Dear TX-Clinical WG Members,

Happy Friday and hope this message finds you well!

A friendly reminder to please help us identify best contacts from whom to solicit compound survey submissions on the antiviral candidates (see below and attached). We would like to send out our outreach communication by COB today. Thank you very much to those who have already responded.

Warm regards,
Helen

From: Chen, Helen Q.
Sent: Thursday, June 25, 2020 4:45 PM
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical WG,

As mentioned during the meeting, our antivirals prioritization team is currently evaluating 11 candidates that have been submitted through the compound survey. In parallel, we would like to actively generate more survey submissions for our team to evaluate in early July.

To that end, **we need your help to identify contacts for additional candidate agents, from whom we will solicit survey submissions.** Please find attached a list of antiviral agents we've identified from public databases, as well as companies / academic institutes affiliated with those agents. Based on your network and industry knowledge, if you could help us fill out the **names and emails of individuals who would be the best contacts for the agents**, that would be much appreciated.

Please return the list to Stacey and me by noon ET tomorrow (6/26). This will allow sufficient time for the investigators to submit the compound survey in time for our next cycle of antiviral prioritization.

Feel free to reach out if you have any questions. Thank you very much!

Warm regards,
Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Wednesday, June 17, 2020 8:48 AM
To: Adam, Stacey (FNIH) [T]; Draghia-Akli, Ruxandra; Garner, Carl; Stein, Peter (FDA/CDER), Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (N H/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (N H/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]
Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, June 25, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom> (b) (6)

Dear ACTIV TX-Clinical WG,

Please find attached the slides that we will use to update on the progress on the master protocols and antiviral prioritization in the last week.

We look forward to speaking with many of you tomorrow.

Kind regards,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/15/2020 3:52:37 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesdener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn | (b) (6) Garner, Carl | (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc8c847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner | (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Philips, L Revell CIV DTRA RD (USA) | (b) (6) Petrovick, Martha - 0449 - MITLL | (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n], Young, John (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]; Salathin, Carla | (b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) Tolman, Brett | (b) (6) Alvarez, Rosa | (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio | (b) (6) Rose Li Central Account | (b) (6) Anderson, Margaret | (b) (6) Lucas Smaldon | (b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. | (b) (6) Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) | (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]

Subject: Summary from ACTIV Therapeutics-Clinical Working Group Meeting 08/13/2020

Attachments: 2020-08-13_TX-Clinical_WG_Meeting_Summary.pdf

Dear ACTIV TX-Clinical WG Members,

Please find attached the summary from our meeting on Thursday. If you have any additions or amendments, please send them to me and I will make sure they are incorporated.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-ME_ENCIOC]
Sent: 8/18/2020 2:23:39 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Do sten, Mikael [(b) (6)]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William [(b) (6)]; Plump, Andrew [(b) (6)]; Stoffers, Paul [(b) (6)]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Coivis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc8d75f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [(b) (6)]; Margaret MA. Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=751c186d094e48959747e0e8f4af87ff-marganderso]; Chen, Helen [(b) (6)]; Elsaid, Olivia [(b) (6)]; Gonzalez, Nina [(b) (6)]; Hawk, Harrison [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Benjamin [(b) (6)]; Tolman, Brett [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Burdow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burdowj]; Castillejos, Carlos [(b) (6)]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; FNIH Central Account [(b) (6)]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Wolinetz, Carrie (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Barasch, Kimberly
 (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne
 (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Perala, Mie
 [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim
 [(b) (6) Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togash, Mieko (NIH/NCI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togash m]; Underwood, Nancy
 [(b) (6)]; Zottoli, Jessica [(b) (6)]; Burrus-Shaw, Cyndi (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hughes, Karen (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugneskp]; Lagos, Enr que
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD)
 [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Tajalli, Ada (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]; Lucas Smalldon
 [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]

Subject: ACTIV EC & Working Group Co-Chair Meeting
Attachments: Materials for September 9 ACTIV Executive Committee Teleconference
Location: <https://fnih.zoom>. (b) (6)

Start: 9/9/2020 6:30:00 PM
End: 9/9/2020 7:30:00 PM
Show Time As: Busy

Required Attendees: Melencio, Cheryl (FNIH) [T]; Collins, Francis (NIH/OD) [E], Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael, Fauci, Anthony (NIH/NIAID) [E], Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin, Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olvia; Gonzalez, Nina; Hawk, Harrison; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]

Optional Attendees: Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account, Gadbois, El en (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carne (NIH/OD) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Peralá, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepuveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]; Lucas Smalldon; Lowy, Doug as (NIH/NCI) [E]

Due to unavoidable conflict, this call is being moved to 2:30 - 3:30 p.m.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
<https://fnih.zoom.us/j/> (b) (6)

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US (Chicago)

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Meeting ID: (b) (6)
Passcode: (b) (6)
number: <https://fnih.zoom.us/j/> (b) (6)

From: Stein, Peter [(b) (6)]
Sent: 4/15/2020 7:30:57 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [Michael.Vincent@pfizer.com]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Rose Li Central Account [(b) (6)]; Lucas Smalldon [(b) (6)]; Salathin, Carla [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Follow-up from ACTIV TX-Clinical WG Agent Prioritization Subgroup - 1st Meeting

I didn't see this in the minutes – but it would be useful to have a master list (dynamic) of ct.gov and other trial registries (exUS) put together – and have each potential repurposed drug for consideration reviewed against already ongoing trials. If we have support to have these registries pulled into a single “dashboard” it would be useful.

We can see what information is available from these registries on the design/size of the trial – as we don't want to prioritize drugs that are already being well studied – unless we wish to consider different uses (eg., ongoing study is for prevention, and we want consider study for later phase treatment). Thus, one criteria to lower prioritization should be that the drug is already being adequately studied. Also, we may want to “bucket” drugs by target – and review the ct.gov/clinical trial registry list by this – so that if there are already 2 drugs with the same target being studied, we would lower the prioritization of another drug with that target (even if it is not itself being studied) – unless the “third” drug has a unique feature that would make it plausible to have efficacy beyond that of the already studied drugs.

peter

From: Adam, Stacey (FNIH) [T] <(b) (6)>

Sent: Wednesday, April 15, 2020 8:42 AM

To: Eric Hughes <(b) (6)> Read, Sarah W (NIH) <(b) (6)> Ruxandra Draghia-Akli
<(b) (6)> Mellors, John W <(b) (6)> Naimish Patel <(b) (6)> Colvis,
Christine M (NIH) <(b) (6)> Young, John <(b) (6)> Stein, Peter
<(b) (6)> Poole, Mike <(b) (6)> Buchman, Tim G (OS)
<(b) (6)> Vincent, Michael <(b) (6)>
Cc: El zabeth Kim <(b) (6)> Menetski, Joseph M (NIH) <(b) (6)> Alvarez, Rosa Maria
<(b) (6)> Rose Li Central Account <(b) (6)> Lucas Smalldon
<(b) (6)> Salathin, Carla <(b) (6)> (b) (6)
(b) (6) Parker, Ashley S (NIH) <(b) (6)> Wholley, David N (NIH) <(b) (6)
Melencio, Cheryl L (NIH) <(b) (6)>

Subject: Follow-up from ACTIV TX-Clinical WG Agent Prioritization Subgroup - 1st Meeting

Dear ACTIV TX-Clinical WG Agent Prioritization Subgroup Members,

Thank you all so much for getting together so quickly for second meeting yesterday. We appreciate all your contributions and I think we made good progress.

Please see attached the high level summary points that we captured, including DRAFT criteria and DRAFT data needed for the criteria. Please let us know your thoughts. Based on this information our co-chairs have created the attached excel spreadsheet as a model for needed data capture. Please let us know your thoughts on this, as well. We will be working to try and turn this into a decision flow diagram for easy review, so your quick response on suggested modifications would be appreciated.

Finally, you will receive this again at the larger WG a little later, but since we were discussing publication and early data/results needs. Please let us know if this publication/literature database exclusively for COVID-19 that NIH has created would be helpful for this purpose.

NIH is supporting a publication database on everything that has been published about COVID-19, generated by NIH Office of Portfolio Analysis (OPA).

- OPA has developed a comprehensive, human-curated portfolio of COVID 19 publications and preprints (<https://icite.od.nih.gov/covid19/search/>)
- This includes peer-reviewed articles from PubMed and preprints from medRxiv, bioRxiv, ChemRxiv, and arXiv. It is updated daily and enables users to leverage the iSearch platform to interrogate manually curated preprints, peer-reviewed publications, and all associated supplemental data from each

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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APAR0000023424-2517681

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 7/24/2020 5:25:36 PM
To: Gadbois, Ellen (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: FW: Summary of the ACTIV Immune Modulator Prioritization Adjudication and Confidentiality Forms
Attachments: 2020-07-22 TX-Immune Modulators Summary.pdf; Therapeutic Clinical Working Group Confidentiality Agreement Individual Template 5-28-2020.docx; Therapeutic Clinical Working Group Confidentiality Agreement Institution Template 5-28-2020.docx

Ellen,

An example of what is going out when we need agreements to review therapeutics.

Joe

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Friday, July 24, 2020 12:57 PM
To: Chen, Helen Q. <(b) (6)> Fessel, Josh (NIH/NHLBI) [E]
<(b) (6)> Deye, Greg (NIH/NIAID) [E] <(b) (6)> Punturieri, Antonello (NIH/NHLBI) [E]
<(b) (6)> McNamara, James (NIH/NIAID) [E] <(b) (6)> Wung, Peter /US
<(b) (6)> Vincent, Michael <(b) (6)> Goff, David (NIH/NHLBI) [E]
<(b) (6)> Garner, Carl <(b) (6)> Robien, Mark (NIH/NIAID) [E]
<(b) (6)> Toggias, Alkis (NIH/NIAID) [E] <(b) (6)> Patel, Naimish
<(b) (6)> Gottesdiener, Keith <(b) (6)> Eric Hughes
<(b) (6)> Aggarwal, Neil (NIH/NHLBI) [E] <(b) (6)> Levy, Elliot
<(b) (6)> Rosenberg, Yves (NIH/NHLBI) [E] <(b) (6)> Buchman, Tim (OS/ASPR/BARDA)
(CTR) <(b) (6)>
Cc: Dana Carluccio <(b) (6)> Rose Li Central Account <(b) (6)>
Read, Sarah (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)> Colvis, Christine
(NIH/NCATS) [E] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Alvarez, Rosa Maria
<(b) (6)>
Subject: Summary of the ACTIV Immune Modulator Prioritization Adjudication and Confidentiality Forms

Dear Agent Prioritization Immune Modulator Subteam,

Please find attached the summary of our adjudication meeting on Wednesday. If you have any additions or amendments, please let us know

In addition, based on our last cycle of reviews, the group expressed a desire to request more information for a few compounds that are requesting CDAs to release the data. In order to obtain this information, we will need to sign a CDA with this group to receive the information. Therefore, we will also need each of you (who is not a government employee) to sign a confidentiality agreement with us, so that we can then share the data with you.

Please find attached the template for the confidentiality agreements that we have been using for any of our ACTIV TX-Clinical WG members that needed to view confidential information. You will see that there are two versions of the confidentiality agreement.

- One version is for those individuals who are able to sign this type of agreement on your own behalf.
- One version is for those individuals whose institutions require that the institutional signatory sign on the individual's behalf.

We provide both options upfront as we may not which will apply to each of you.

Please review the confidentiality agreement and send back the signed copy as soon as you can. Once we have all of these signed and the information from the agent teams, we will circulate to the group for final review and decision on that agent. Please note, if you signed one of these for the Antiviral group, it will apply this one as well and you do not need to sign another.

Please return your signed agreement to Helen or myself as soon as you can. If you have any questions, do not hesitate to reach out.

Thanks,
Stacey

Stacey J. Adam, PhD
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From: Stan Erck | (b) (6)
Sent: 7/10/2020 10:35:05 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Mary Riggini
[(b) (6)]
Subject: Re: Invitation to Join ACTIV Leadership Team

Francis, thanks for the invitation. I would be happy to join. I'm cc'ing Mary Riggini who is the master of my schedule. Look forward to it. And, I'd prefer "Stan" to Mr. Erck. Look forward to seeing you.

Best, Stan

From: "Collins, Francis (NIH/OD) [E]" < (b) (6)>
Date: Thursday, July 9, 2020 at 10:23 PM
To: Stan Erck < (b) (6)>
Cc: "Wholley, David (FNIH) [T]" < (b) (6)>
Subject: Invitation to Join ACTIV Leadership Team

[SENDER IS EXTERNAL TO NOVAVAX]

Dear Mr. Erck,

I greatly appreciate Gregory Glenn serving on the ACTIV vaccines working group as a representative for Novavax. We have lots of activity across our ACTIV working groups moving at rapid speed. ACTIV (Accelerating COVID-19 Therapeutic Interventions and Vaccines) has a leadership team that meets once a month to discuss progress and we typically invite the CEO's of the biotech companies to join. It would be great to have you join future leadership meetings to represent Novavax as a partner.

Please let me know if you would be able to join our leadership team and David Wholley, cc'd who manages the ACTIV partnership will ensure you receive the meeting invite for our next meeting scheduled for Wednesday, July 29, 2:30-4:00pm.

Thanks,
Francis

Francis Collins M.D., Ph.D.
NIH Director

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 2/14/2021 12:10:49 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: [EXTERNAL] a few follow ups

Francis –

Happy to join this call. It's hard to tell from Mikael's note below, but it sounds like besides clinical testing there may be some interest in getting manufacturing support from USG (thus Albert Bourla). Do you want someone on that call who could address it (not sure who that would be)?

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Saturday, February 13, 2021 11:17 AM
To: Dolsten, Mikael <(b) (6)>
Cc: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> Barasch, Kimberly (NIH/NIAID) [E] <(b) (6)> Conrad, Patricia (NIH/NIAID) [E] <(b) (6)>
Subject: RE: [EXTERNAL] a few follow ups

Hi Mikael,

I've discussed with Tony, and we are very interested in meeting with you and your team. I'd like Tony, Cliff Lane, David Wholley, and me to join, and you can decide which of the Pfizer team would be most essential.

I'm looping in Gretchen Wood who can work with your Pfizer team to find a good time for this. Tuesday may be a challenge, but all of us will seek to move calendars around if necessary.

Best, Francis

From: (b) (6)
Sent: Friday, February 12, 2021 2:32 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> <v>
Subject: Re: [EXTERNAL] a few follow ups

Francis

If you prefer a smaller group, I am pleased also to present the protease drug highlights myself and join together with our CEO Albert Bourla from Pfizer to meet the three of you

Best
Mikael

Sent from my iPhone

On Feb 12, 2021, at 14:16, (b) (6) <(b) (6)> wrote:

Dear Francis

I and our Pfizer CEO Albert Bourla just reviewed the clinical plans from our protease inhibitor team . We also assessed manufacturing needs (for EUA) to possibly plan for success with time lines for potential EUA already in 2021 or early 2022 (pending good data of course).

We would enjoy as you suggested below meeting you , Tony and David as soon as possible - maybe Tuesday next week (Monday is holiday) to discuss how we can work together on our IV and ORAL pan-Corona virus protease inhibitor (Pi) drugs .

In this time of SARSCov2 viral evolution , they seems like a drug class w great promise .

We have submitted the IV PI drug to ACTIV w positive reception . We are planning to submit the oral PI drug to ACTIV on Wednesday next week .

Albert will join me in the meeting w you. If you want to have some more detailed background science on the drugs , I was thinking to bring in our two key scientist leaders in this area eg Liesa Anderson and Charlotte Allerton . Liesa participated in ACTIV since the start within therapeutics related work streams .

Look forward to your response

Best
(b) (6)

Sent from my iPhone

On Feb 11, 2021, at 05:26, Collins, Francis (NIH/OD) [E] (b) (6) > wrote:

Hi (b) (6)

Thanks for quick response to my message – and wow, the progress on the oral anti-protease is fantastic! In the face of rising concerns about viral variants in the spike protein, the efficacy against all coronaviruses is extremely encouraging – will this even cure the common cold? 😊 I am sure the ACTIV team would be ready to move quickly to slot this into ACTIV-2/3, pending the results of your phase 1 SAD-MAD studies. Considering possible combination therapies could also be a very appealing next step.

Let me know when you are ready to discuss – I'd like to bring Tony Fauci and David Wholley into that conversation soon.

Best, Francis

From: (b) (6)
Sent: Wednesday, February 10, 2021 8:36 AM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Subject: Re: [EXTERNAL] a few follow ups

Hi Francis

Good that you try to correct NYT article but TIME paper was great

The exciting piece w the antiviral protease inhibitor (PI) drugs is that they are pan-corona virus active w potential as a drug for any new pandemic coronavirus. They also will inhibit all presently known SARSCov2 mutant variants that mainly affect SPIKE

Confidential update

(b) (4)

(b) (6)

Sent from my iPhone

On Feb 10, 2021, at 06:33, Collins, Francis (NIH/OD) [E]

(b) (6) wrote:

Hi (b) (6)

Just checking in. First, thanks for your kind words that were quoted in the TIME magazine profile – very much appreciated!

Second, I have been distressed by the uninformed characterization of the ACTIV efforts on therapeutics in the New York Times article ten days ago by Carl Zimmer, and a more recent OpEd from Zeke Emanuel et al. The TIME article gave a much more accurate depiction, and I hope that was noticed. My staff and I are working in other ways to correct the record on this – including an upcoming New Yorker article and 60 Minutes segment that will be much more positive!

Third, I am glad to see positive momentum in moving forward with the Pfizer anti-protease therapeutic through ACTIV. I hear good things about PF-07304814, and the potential for entering this into the ACTIV-3 trial in the near future. Of course I'm also intensely curious about your progress with an oral anti-protease, since that could be a true game-changer for this pandemic – and an advance desperately needed at a time where new SARS-CoV-2 viral variants are causing a lot of concern. Anything you can tell me about progress there?

All the best, Francis